UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

In re: SMITH & NEPHEW BHR HIP IMPLANT PRODUCTS LIABILITY LITIGATION	)	MDL No. 2775
This Document Relates to:	)	JURY TRIAL DEMANDED
All Cases	)	

MASTER AMENDED CONSOLIDATED COMPLAINT

INTRODUCTION

1. This is a products liability lawsuit related to a dangerous and recalled metal-on-metal ("MOM") hip implant. This Master Amended Consolidated Complaint ("MACC") is being filed in the District of Maryland in MDL 2775, *In re: Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liability Litigation*, pursuant to Case Management Order 3.

2. Smith & Nephew, Inc., ("S&N" or "Smith & Nephew" or "Defendant") designed, manufactured, and sold a dangerous and defective product, the Birmingham Hip Resurfacing System ("BHR") in the United States beginning in 2006.

3. Plaintiffs ("Plaintiffs" or "patients") bring this case to seek compensation for injuries suffered as a result of Smith & Nephew's negligence, arising from violations of statutory and common law. Despite Smith & Nephew's repeated representations that all of Plaintiffs' claims are preempted by federal law, Smith & Nephew is liable to Plaintiffs under state law claims for negligence, strict products liability, negligent misrepresentation, breach of warranty and manufacturing defects which operate independently from and are parallel to federal law.

4. Further, Smith & Nephew's only basis for attempting to assert preemption protection is that the FDA approved the BHR product through the Pre-Market Approval ("PMA") process. However, the PMA included numerous conditions that Smith & Nephew never actually met or completed before recalling the BHR because it was unsafe. Accordingly, the federal preemption defense associated with some PMA devices does not act to bar any of Plaintiffs' state law claims. Smith & Nephew also failed to adhere to FDA-mandated manufacturing practices, which, upon information and belief, resulted in manufacturing defects in Plaintiffs' devices.

5. Further, upon information and belief, based on available evidence, and based on reasonable inferences drawn from that evidence, Smith & Nephew continued selling a dangerous metal-on-metal hip despite overwhelming evidence that it was unsafe and that *all* metal-on-metal hips were unsafe. Smith & Nephew did this because it believed it could avoid all legal liability. But despite Defendant's hope for corporate immunity, federal law does not preempt state law under these circumstances, nor should it.

PARTIES

6. Plaintiffs are citizens and/or residents of the United States who experienced severe personal injuries, medical complications, and damages from the implantation of the Smith & Nephew BHR.

7. Defendant, Smith & Nephew, Inc., is and at all times relevant to this action was a resident and/or corporation with its principal place of business in Memphis, Tennessee.

JURISDICTION

8. Complete diversity of citizenship exists pursuant to 28 U.S.C. § 1332, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

9. This Court has jurisdiction over S&N because it does business in this forum, including with some Plaintiffs in this case, and pursuant to 28 USC § 1407.

FACTUAL BACKGROUND

10. Smith & Nephew is a wholly owned subsidiary of Smith & Nephew, plc, a public entity incorporated under the laws of England and Wales. Smith & Nephew is a global medical technology company, with a presence in more than 90 countries worldwide, and total sales of $4.67 billion in 2016.

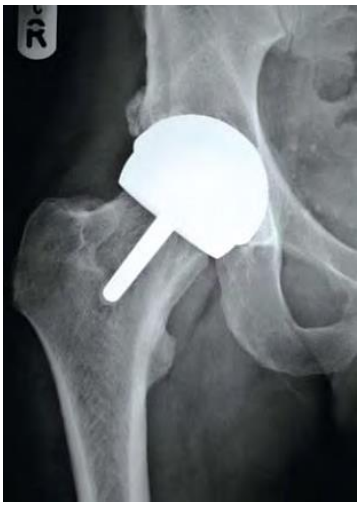
11. Smith & Nephew markets, manufactures, and sells prosthetic hip devices for use in total hip arthroplasty and resurfacing arthroplasty, specifically the hip socket, or acetabulum, and the ball, or femoral head. These hip replacement products include the BHR, which Smith & Nephew recalled on September 10, 2015, due to high failure rates, especially for female patients and for patients with small joint sizes.

I. The Birmingham Hip Resurfacing Device and S&N's Recall

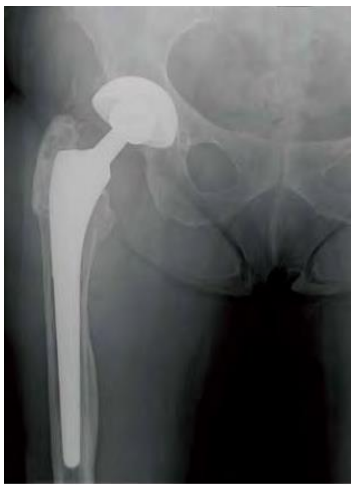
12. Smith & Nephew is a designer, developer, manufacturer, marketer, and seller of joint replacement systems. Since at least 2006, and in some cases, before 2006, Smith & Nephew has manufactured, introduced, and/or delivered the BHR into the stream of interstate commerce. The BHR is a metal-on-metal hip resurfacing prosthesis compromised of the following two (2) components: the Birmingham Resurfacing Femoral Head and the Birmingham Hip Resurfacing Acetabular Cup.

13. In a resurfacing arthroplasty, the femoral head is not removed but is instead trimmed and capped (resurfaced) with a smooth metal covering. This procedure differs from a total hip arthroplasty replacement ("THA"), which includes the placement of a prosthetic femoral stem:

BHR:



THA:



14. The BHR femoral head and a hemispherical acetabular cup are made in a range of twelve (12) sizes. The cup fits into the patient's hip socket, or acetabulum, and then rubs against the femoral head during articulation (movement) of the patient's hip joint. Both components are made of cobalt and chromium metal alloys, and thus are "metal-on-metal" hip implant components.

15. Articulation of the components as the hip joint moves creates metal-on-metal friction and causes metal debris to enter the space around the hip implant and the bloodstream. The metal debris and metal ions cause physiological reactions in patients, often beginning with swelling and pain. This metal wear continues causing damage to surrounding tissue and bone resulting in implant metallosis, ALVAL, adverse reaction to metal debris, pseudotumor, premature loosening, and ultimately device failure requiring a revision surgery. Toxic levels of metal ions in the patient's bloodstream also cause neurological and cardiac problems and organ failure.

16. Revision of a failed BHR typically requires a conversion to a total hip replacement, including implantation of a traditional stem. Further, Smith & Nephew knew it did not have FDA approval for a modular metal femoral head for use with a BHR cup. Therefore, any patient requiring revision surgery and conversion to a total hip replacement required removal and revision of the acetabular cup as well, even if the cup is well fixed. Premature revision of the acetabular cup requires removal of the old cup, re-reaming of the acetabulum, and implantation of the revision cup. Revision of a BHR resurfacing system is thus more damaging to the patient than revision of other total hip products like the DePuy ASR where the acetabular cup is often left in place during the revision surgery. Smith & Nephew never received approval from the FDA to sell the components necessary to perform a revision surgery.

17. Even though S&N knew or should have known that revision of a BHR is more damaging than revision of a THA, and knew that there was no FDA-approved device to convert the BHR to a THA, S&N marketed BHR specifically to younger, more active patients who were certain to need future revision of their BHR implant. Smith & Nephew then encouraged these patients to perform activities that would generate extreme amounts of metal debris and metal

particles, including marathons, long-distance competitive cycling, martial arts, skydiving, and downhill skiing.

18. Smith & Nephew first recalled numerous versions of the BHR in 2007 due to labeling problems and other issues.

19. In August 2010, the DePuy ASR metal-on-metal hip prosthesis was recalled, confirming for Smith & Nephew the dangers of its similar metal-on-metal BHR device. Clinical analysis of the ASR and BHR devices confirmed the BHR had a similar linear wear rate for certain components and generated similar levels of metal ions compared to patients implanted with the ASR. *E.g.*, Underwood, et. al., *A Comparison of Explanted Articular Surface Replacement and Birmingham Hip Resurfacing Components*, J. Bone Joint Surg. 2011 Sep; 93(9); 1169-77.

20. Smith & Nephew had numerous chances to follow the lead of its competitors such as the Zimmer (Durom), DePuy (ASR & Pinnacle), Biomet (M2a Magnum), and Wright (Conserve), all of which were metal-on-metal devices recalled or otherwise removed from the U.S. market in the years before the BHR. But Defendant chose to keep selling the BHR for years, despite these warning signs.

21. On June 4, 2015, Smith & Nephew announced the voluntary removal of the BHR device from the U.S. market due to unreasonably high failure rates for certain demographic groups, including all women, all men age 65 or older, and all men requiring femoral head sizes 46 mm or smaller. However, Smith & Nephew failed to notify physicians and patients at this time about the need for metal ion testing, imaging, and other conservative measures to diagnose metal-on-metal failure in patients with BHR devices. For many of these patients, this resulted in delayed testing and/or awareness about the health hazards posed by their BHR devices.

22. The market withdrawal of the BHR followed numerous other warning signs, including an Urgent Field Safety Notice sent to doctors in November 2014 about high revision rates for the same population groups mentioned above, and for patients with congenital dysplasia, and diagnosed avascular necrosis. At the time, Smith & Nephew promised that it would implement further measures to warn patients and surgeons about "the steps they should be taking," but on information and belief, and available discovery, Smith & Nephew never implemented these measures, and never fully informed patients and surgeons of the full risks associated with metal-on-metal failure of the BHR device.

23. Smith & Nephew should have recalled the BHR long before September 2015, and if it had complied with both its state law duties outlined below and the terms of the PMA, it would have recalled the BHR much earlier than it did. As a result of its failure to do so, Plaintiffs were harmed through implantation of a device that they otherwise would not have received, and by delayed revision surgery and delayed testing for metal-on-metal failure.

II. Smith & Nephew Misrepresented to the FDA and Medical Community the Safety of the BHR, Especially for Women and Patients Requiring Smaller Device Size

24. Smith & Nephew misrepresented to the medical community, patients, and the FDA the safety of the BHR, especially the safety of the device for women, older men and patients requiring smaller BHR head sizes.

25. Smith & Nephew's misrepresentations were made in the product labeling, patient information sheet, and instructions for use ("IFU") of the BHR.

26. Additionally, Smith & Nephew's misrepresentations were made in communications and advertising outside the labeling and IFU, were made in communications directly to implanting surgeons, were made in communications directly to patients and Plaintiffs, were made in communications to the medical community and public at large, and were made

directly by Smith & Nephew employees, agents, and sales representatives to surgeons, patients, Plaintiffs and/or the medical community.

27. Smith & Nephew directly represented to patients, including Plaintiffs, that the "BHR Hip allows surgeons to resurface your joint with a safe and effective metal implant."

28. Not only was this not true, it also went beyond the FDA-approved labeling. This statement was more than mere sales language—it was included in a longer document directed to the medical community and/or patients that included scientific and medical language, citations to medical journals, pictures, and information that appeared authoritative so that reasonable readers, including patients and Plaintiffs, would believe that the BHR was actually safe. This was more than simple puffery or generic descriptions of the product; it was a specific representation to doctors and patients about the safety of the BHR device.

29. That patient information sheet, also called an "outsert", was specifically intended to reach Plaintiffs and patients, specifically intended to influence patients' and Plaintiffs' choice of the BHR implant, and actually was viewed and did influence Plaintiffs:

smith&nephew
BIRMINGHAM HIP®
Resurfacing System

The BIRMINGHAM HIP Resurfacing (BHR®) System

A safe and effective metal-on-metal hip resurfacing implant

The BHR Hip is made from metal. How does that compare to other options, like plastic or ceramic?
All bearing materials used in hip implants have advantages and disadvantages. For instance, metal-on-metal implant surfaces are very durable. The largest independent follow-up study showed that greater than 95% of BHR Hips remain fully functional after ten years of use.[1] The BHR Hip is made from a special "as-cast" metal that's been proven in long-term metal-on-metal hip implants, and it doesn't carry with it the fracture risk of ceramic hips or the reduced wear properties of a plastic component.

What are metal ions?
Metal ions are tiny particles of metal released over the lifespan of the device. All hip replacement implant materials (plastic, metal and ceramic) release small particles during typical use, but differences lie in the amount and types of particles. The BHR Hip releases mostly cobalt and chromium ions in very small amounts. These elements are already in your body, even before you receive a BHR Hip (cobalt is a cofactor in vitamin B12, while chromium is involved in insulin uptake), and your kidneys filter them from your system.

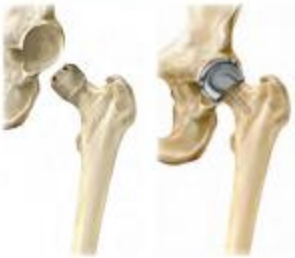
The amounts of these metal ions released from a properly implanted BHR Hip are so small that they're measured in a unit called a micron. For perspective, a human hair is about 100 microns in diameter. In a properly implanted BHR Hip, the typical rate of release is about three to five microns during what's known as its initial "run-in" phase, then only a few microns per year thereafter.

I've heard about "pseudotumors." Is this a risk?
"Pseudotumor" is a term that's used to describe local swelling or masses. It's been discussed more widely recently due to a paper published by a group of surgeons in Oxford, England, following a series of benign tissue masses found in a small group of resurfacing patients. These tissue reactions can occur with any hip or knee replacement or resurfacing implant—they are not cancerous tumors.

Additionally, these reactions have occurred in less than 0.09%-0.32% of BHR Hip patients[2,3] and it's believed that they could be caused by either the patient's metal allergy or sensitivity or by excessive wear caused by poor implant positioning. For perspective, studies show that the risk of dislocation following a patient's first hip replacement surgery is many times greater than the risk of a tissue reaction. So while an adverse tissue reaction may be considered a potential risk, it is a very rare occurrence for BHR Hip patients.

How long will the BIRMINGHAM HIP Resurfacing implant last?
It is impossible to say how long your implant will last because so many factors play into the lifespan of an implant. In the case of the BHR Hip, for instance, the metal-on-metal bearing surfaces of your new joint may extend its life longer than that of a total hip replacement made from traditional materials, but failure to comply with your physical rehabilitation regime may cause your implant to fail prematurely. A clinical study showed the bone-preserving BHR Hip had a survivorship of 95.4% at the ten-year mark, with 98.6% of patients saying they were "pleased" or "extremely satisfied" with their implant.[1]

1. Robinson E, Richardson JB, Khan M. MINIMUM 10 YEAR OUTCOME OF BIRMINGHAM HIP RESURFACING (BHR), A REVIEW OF 518 CASES FROM AN INTERNATIONAL REGISTER. Oswestry outcome centre, Oswestry, UK.
2. Beaule PE, Smith FC, Powell JN et al. A Survey on the Incidence of Pseudotumours with MOM Hip Resurfacings in Canadian Academic Centres. Podium presentation # 665. Proceedings of the American Academy of Orthopaedic Surgeons Annual Meeting, New Orleans LA. 2010
3. Australian Orthopaedic Association National Joint Replacement Registry Annual Report. Adelaide: AOA; 2008



The BHR Hip allows surgeons to resurface your joint with a safe and effective metal implant.

Hip resurfacing surgery is intended to relieve hip pain and improve hip function. There are potential risks with hip resurfacing surgery such as fracture, infection, loosening, dislocation and wear that may result in the need for additional surgery. Females of child-bearing age should not have the BHR device. It is unknown whether metal ions released by the device could harm an unborn child. Do not perform high impact activities such as running and jumping during the first post operative year while the bone is healing. Early device failure (breakage or loosening) may occur if you do not follow your surgeon's limitations on activity level. Early failure can happen if you do not guard your hip joint from overloading due to activity level, failure to control body weight, or accidents such as falls. Talk to your doctor to determine what treatment may be best for you. Additional BHR Hip patient information is provided at www.bhrhip.com.

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30. The misrepresentations made in that document, discussed in more detail below, were not the only representations Smith & Nephew made to Plaintiffs and patients, but are one

example, and can form the basis for negligence, negligent misrepresentation, warranty, and strict products liability and failure to warn claims that exist wholly apart from the FDA-approved labeling.

31. Had Plaintiffs and patients known the truth about the safety and efficacy of the BHR, and if Smith & Nephew had communicated the truth about the safety of the BHR, Plaintiffs and patients would not have chosen the BHR for their hip implant.

A. Smith & Nephew Had a Duty to Be Truthful In Its Voluntary Statements Made Outside the Warning Label, In Separate Communications Made Directly To Physicians and Patients

32. Smith & Nephew had a duty under the laws of the various states where Plaintiffs reside to be truthful in its voluntary statements, representations and warranties about the safety of the BHR, including, but not limited to, Dear Doctor Letters, surgeon training materials, all advertising and promotional materials, IFUs, brochures to surgeons, press releases, direct-to-patient communications such as patient pamphlets, websites and other materials, and communications by its sales representatives.

33. Smith & Nephew had a duty to disclose to Plaintiffs, Plaintiffs' surgeons and the medical community the truth about the safety of the BHR resurfacing products because Smith & Nephew was in a superior position to know the true quality, safety, and efficacy of the BHR resurfacing products.

34. Smith & Nephew also had a duty to disclose — and not omit — all material facts about the safety of the BHR in its voluntary statements, representations and warranties about the safety of the BHR, including, but not limited to, Dear Doctor Letters, all advertising and promotional materials, IFUs, brochures to surgeons, press releases, direct-to-patient

communications such as patient pamphlets, websites and other materials, and communications by its sales representatives.

35. Smith & Nephew had a duty to be truthful to the FDA about the safety of the BHR in all its communications under, for example, 21 U.S.C. 360e(c)(2)(A)(x).

36. Smith & Nephew had a duty to disclose all material facts, and not omit any material facts, to the FDA under, for example, 21 U.S.C. 360e(c)(2)(A)(x).

37. The acts and omissions complained of here violate state law as well as the independent and parallel federal duty to be truthful to and disclose all material facts to the FDA as described above. Plaintiffs are not bringing independent claims for fraud on the FDA.

B. Smith & Nephew Misrepresented the Safety of the BHR to the Medical Community and Plaintiffs

38. Smith & Nephew represented to patients and Plaintiffs, to surgeons and the medical community, and to the public at large that the BHR was safe. These false and misleading statements, representations and warranties both explicitly and implicitly implicated the safety of the BHR for patients, including Plaintiffs, and were intended to communicate the safety of the device beyond what was contained in the FDA-approved warning label and IFU.

39. Contrary to Smith & Nephew's representations, training and marketing to the medical community and to the patients and Plaintiffs themselves, the BHR has high failure, injury, and complication rates, fails to perform as intended, requires frequent and often debilitating re-operations, and has caused severe and sometimes irreversible injuries, conditions, and metal-on-metal damage to a significant number of patients, including Plaintiffs.

40. Smith & Nephew represented to the medical community and to patients that the BHR was safe by comparing it to other metal-on-metal devices and promoting the BHR as a safe alternative, long after it knew or reasonably should have known of the risk of premature metal-on-

metal failure, and did not withdraw the device from the U.S. market until 2015. Plaintiffs were the intended recipients of those representations and did in fact receive them and rely upon them, either directly, through their medical professionals, or both.

41. Smith & Nephew made numerous false and misleading claims to the general public, the medical community and to Plaintiffs in particular, that the BHR devices were safe for their intended use and that they did not suffer from the same problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary. For example, on February 9, 2012, S&N's senior vice president publicly touted in a press release the BHR as being "unlike any other metal-on-metal hip implant" with a survivorship rate superior to even traditional non-metal devices due to its "distinctive metallurgy heritage" and other factors. Additional press releases contained the same or similar representations on May 4, 2010, and December 7, 2007.

42. Smith & Nephew directly told patients and the medical community that the BHR was safer than ceramic hips because there was less of a risk of fracture than ceramic hips.

43. Smith & Nephew directly told patients and the medical community that the BHR was safer than ceramic hips because there was less wear than ceramic hips.

44. Smith & Nephew directly told patients and the medical community that the BHR releases cobalt and chromium ions "in very small amounts," that patients already have cobalt and chromium in their body (even implying that cobalt was good for patients because it is part of the vitamin B12), and that the patients' kidneys would "filter them from your system."

45. Smith & Nephew directly told patients and the medical community that the amounts of cobalt and chromium ions released into the patients' bodies by the BHR were so small they were measured in a unit called "microns" and that only 3-5 microns were introduced into the body initially, and then only a few microns per year were introduced into the body.

46. In an April 2011 patient information sheet, and upon information and belief earlier than that, Smith & Nephew directly told patients and the medical community that pseudotumors are "benign" and are caused by the patients' own "metal allergy sensitivity" or by the surgeon using "poor implant positioning." Smith & Nephew directly told patients that adverse tissue reaction is a "very rare occurrence for BHR Hip patients" and that there was a much greater risk of dislocation than pseudotumors or adverse tissue reaction.

47. This communication to patients and the medical community was made *after* the FDA ordered Smith & Nephew to add pseudotumors to its labeling, which occurred in December 2009 and early 2010. Thus, Smith & Nephew went beyond the FDA-approved labeling and in fact undercut the FDA-approved labeling in its communications directly to the medical community, patients and Plaintiffs about the safety of the BHR.

48. Smith & Nephew represented to patients and the medical community that the BHR "may" last longer than total hip replacement using ceramic surfaces, but that if it didn't, it was because the patient failed to comply with their "physical rehabilitation regime" and not because of the BHR.

49. Smith & Nephew also represented to patients and the medical community that the BHR resurfacing device was safer than metal-on-metal total hip replacements, even though its own testing showed that the BHR generated far higher levels of chromium ions in patients compared to its own total hip replacement device, which includes a Birmingham cup and a modular femoral head and stem. For example, in a study conducted by BHR designer Derek McMinn and others, Smith & Nephew reported that patients implanted with the company's modular total hip replacement system had mean chromium ion levels nearly twice as high as patients with the BHR resurfacing device (2.4, compared to 1.4).

50. Smith & Nephew represented to patients and the medical community that the BHR was safe because one study found 95.4% survivorship at 10 years and 98.6% of patients saying they were "pleased" or "extremely satisfied" with their BHR. In part because of flaws in the study's methodology and lack of follow-up of patients, as described in more detail below, the results of this study were not matched and could not be matched by any real world data and Smith & Nephew never corrected this false impression or updated patients on the real world data that contradicted the results of the this study.

51. Smith & Nephew pointed patients and the medical community to a website, www.bhrhip.com, which included the quotes reproduced below as direct-to-patient statements that were false, misleading, and/or omitted material information:

a. 2009 Australian Registry's results showed BHR Hip's survivorship at 8 years (95%) is better than all other resurfacing implants' survivorship after just their 5th year.

b. 2008 Australian Registry's study found that resurfacing devices outperformed total hip replacement for men under age 55, as well as ages 55-64.

c. Great Britain's Owestry Outcomes Centre's patient registry revealed BHR Hip's 10-year survivorship of 95.4%, with 98.6% of patients rating their opinion of the experience as "pleased" or "extremely pleased."

d. A study presented at the American Academy of Orthopaedic Surgeons 2010 Annual Meeting discussed importance of several factors in successful outcomes of resurfacing hip replacements. One factor was prosthesis selection, and it showed that BHR Hip had a significantly lower risk of revision than other hip resurfacing options.

e. The BIRMINGHAM HIP was introduced in 1997 and has been unchanged since that time. All the other metal-on-metal resurfacings available worldwide today were introduced after the BIRMINGHAM HIP and are based in part on the BIRMINGHAM HIP design. Most companies wanted to change their design to try to differentiate from the leader, and today, these design changes have not been shown to be an improvement. Whether it is the metallic properties, the way it is held to the bone, or the sizing, these changes have not been shown to have the success the BIRMINGHAM HIP has had. Remember, the BIRMINGHAM HIP is proven to successfully treat hip arthritis in younger, more active patients.

f. In the clinical study provided to the FDA, the BIRMINGHAM HIP showed a 98% success rate at 5 years. Less than 2% needed to be revised for any reason. Most other devices haven't been around long enough to have results published. On the two longest competitors, published results show a much lower success rate, of 92% and 95% at shorter follow up times. Because these are resurfacing components, the patients were probably able to get a total hip replacement after failure, but the results appear to be significantly inferior to those of the BIRMINGHAM HIP.

g. The BIRMINGHAM HIP is one of the most studied modern hip implants. Over two dozen peer reviewed articles have been published evaluating the BIRMINGHAM HIP performance. Some of the landmark papers are:

    i. Treacy - a minimum 5 year follow-up of the first 144 patients. Only 3 failures during this time.

    ii. McMinn - a comparison of resurfacing and replacement in patients under 55 years of age. Resurfacing fared much better in the mid-term of 4-7 years.

The BIRMINGHAM HIP Resurfacing had 4 year results with success of 98%

iii. Shimmin – Success of 99% in first 230 cases

iv. DeSmet – Over 98% success

v. Sugano – 96% success at 5 year minimum

(citations omitted).

52. Smith & Nephew made these false and misleading representations as early as 2008 on its website, and in a direct-to-patient "outsert" that Smith & Nephew provided surgeons to give to patients beginning in at least 2010 and through 2011 and at least 2012, if not later. Upon information and belief, the website was available until the recall of the BHR.

53. Plaintiffs viewed these representations, including the BHR websites, and received this information either directly from Smith & Nephew and/or through their surgeons and the information contained therein influenced Plaintiffs' decisions to undergo the resurfacing procedure and have the BHR implanted in them. Smith & Nephew intended these websites, patient information sheets and other direct-to-consumer materials to influence Plaintiffs, their surgeons and patients and for Plaintiffs, their surgeons and patients to rely upon them.

54. Smith & Nephew was aware that patients, Plaintiffs, and their surgeons, would view these websites, direct-to-patient information sheets, leaflets, pamphlets, and/or outserts, was aware that Plaintiffs would rely upon the information in these documents in making the decision to choose the resurfacing procedure and the BHR implant, in consultation with their surgeons, and Smith & Nephew intended these marketing materials to influence patients', Plaintiffs' and their surgeons' decision to choose the BHR.

55. These are examples of direct-to-consumer marketing materials, and upon information and belief, Smith & Nephew made additional misrepresentations, warranties and voluntary statements to Plaintiffs and patients with similar misrepresentations about the safety of the BHR.

56. These representations were false or misleading because they were either actually false or because they omitted material facts known to Smith & Nephew at the time of the misrepresentations and/or that should have been known to Smith & Nephew at the time of the misrepresentations and/or that Smith & Nephew later learned but neglected to update, inform or correct the previous misrepresentations, including, but not limited to:

a. The BHR was not safe.

b. Metal-on-metal hips are unsafe regardless of the different features among them.

c. Metal-on-metal hips are not as safe as ceramic hip products.

d. Failure rates in women and in patients with smaller head sizes were much higher than in men and other patients, and the overall failure rates were actually higher than those reported by Smith & Nephew.

e. The inclusion of men, women and all head sizes in failure rates masked the true failure rates among women and patients with smaller head sizes;

f. The studies that Smith & Nephew represented as proof the BHR was safe were done by McMinn and Treacy, both of whom were the surgeons who designed, developed and sold the BHR to Smith & Nephew. McMinn believed that the learning curve for the BHR was more than 1,000 surgeries, and Smith & Nephew promoted the BHR to hundreds of U.S. surgeons even though it knew most of them would never perform enough hip resurfacings to master the learning curve.

Therefore, these survivorship numbers were misleading and could not be replicated in the real world.

g. That metal ions in any amount were harmful to patients, and could lead to pseudotumors, adverse reaction to metal debris, ALVAL, and other indicia of metallosis.

h. That there was no evidence that patients had hypersensitivity to metal ions and that it made them more likely to need revision, no specific tests made available to patients before their surgeries, and no evidence that it was patients' fault that their hip products produced metal debris.

i. That metal ions produced by the BHR were higher than were naturally found in the body.

j. That an adverse reaction to metal debris causing the need for revision might take longer than 5 years, making the data about 5-year survivorship incomplete and irrelevant to the safety of the device.

k. That McMinn's studies lost track of numerous patients after 5-years when failure rates are more likely to go up.

l. That real-world failure rates were higher than early clinical studies on which Smith & Nephew relied.

m. That revision of a resurfacing product was worse for the patient than a total hip revision, that revision of a resurfacing product required the conversion to a total hip revision, and that the BHR was not approved in the United States for use in a total hip, forcing surgeons to take out *all* of the BHR components, even if they were fully fixed and attached to the patient's body.

n. Smith & Nephew represented that the BHR components were of a particular standard, quality and/or grade, and they were not.

o. Smith & Nephew engaged in false and misleading conduct that led surgeons and the medical community to believe and understand that the subject components were safe, effective, permitted and intended to be used with one another when they were not and with the knowledge that the use of the subject components together would lead to serious injury and/or harm to patients in which they were used.

57. In sum, Smith & Nephew for years made voluntary statements outside the labeling and directly to the medical community and to patients, including Plaintiffs, that the BHR was safe. This message was delivered explicitly and implicitly, was designed to convey that the BHR was safe, went beyond mere descriptive puffery and was a material factor in patients choosing a BHR and/or choosing to agree to their doctor's recommendation (which was also secured by Smith & Nephew through false and misleading representations beyond the FDA-approved labeling) to undergo hip replacement surgery using a BHR.

58. Had Smith & Nephew been truthful in its statements and included material information that it actually omitted, surgeons would not have recommended and patients would not have chosen the BHR and would have chosen a safer option, including but not limited to total hip replacement devices and/or total hip replacement devices using ceramic materials. Patients with existing BHR devices implanted in their bodies also would have undergone testing and imaging to minimize the risks associated with metal-on-metal failure, including but not limited to metal toxicity, pseudotumor, ALVAL, and adverse reaction to metal debris.

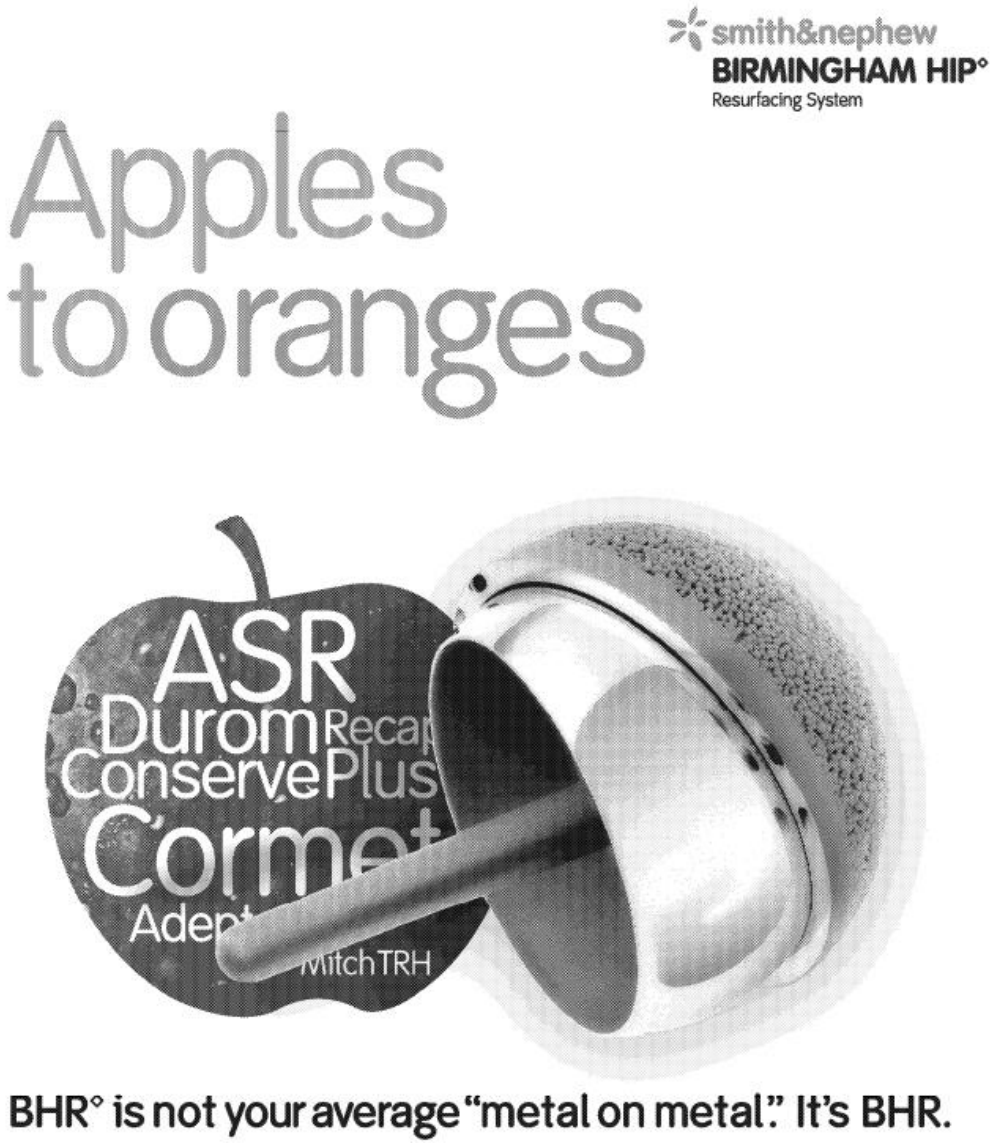
59. Smith & Nephew made voluntary statements outside the FDA-approved labeling to surgeons and the medical community about the safety of the BHR. These statements both

explicitly and implicitly conveyed the message the BHR was safe, was safer than other metal-on-metal devices, was safer than total hip replacement, and was safer than ceramic hip devices. None of those statements were true, and had Smith & Nephew made true statements and included material information that it had omitted regarding the safety of the BHR, surgeons would not have recommended to their patients, including Plaintiffs, that they undergo hip resurfacing using the BHR. Further, Smith & Nephew provided information from sources that, over time, published new and updated information. Smith & Nephew failed to provide this new and updated information which cast doubt or definitively proved that the BHR and all metal-on-metal hips were not safe. All of these voluntary statements and representations went beyond the information included in the FDA-approved labeling.

60. Smith & Nephew made representations to the medical community in its surgical guide, both directly and through inventor and designer Mr. Derek McMinn, that were not true and/or misleading, and misrepresented the safety of the BHR to the medical community.

61. Specifically, the 2011 surgical technique document referred to the hip implant as an "uncomplicated procedure" when in fact McMinn believed that it was a procedure with a 1,000 patient learning curve. Smith & Nephew did not notify the FDA of the 1,000 patient learning curve, and therefore this action violates both state law duties as described below and the independent and parallel duty of truthfulness to the FDA.

62. Smith & Nephew had numerous communications and made numerous statements to physicians. One example is the "Apples to Oranges" communications made in 2010:



63. As proof that the BHR was "not your average 'metal on metal' hip, Smith & Nephew cited one study (the same one it cited to patients) showing 95.4% 10-year survivorship. The results of this study were false, misleading and contradicted by real-world performance of the BHR, which Smith & Nephew knew at the time it made these representations. To the extent it became clear later that the BHR failure rates were much higher than the studies touted by Smith

& Nephew, Smith & Nephew never updated the medical community and never corrected this false impression, despite knowing it was untrue and misleading.

64. In 2010, Smith & Nephew sent a letter to surgeons that constituted voluntary statements outside the FDA-approved labeling about the safety of the BHR, including representations about metal ions. Despite early advertising and communications to surgeons relying on the Medicines and Healthcare products Regulatory Agency ("MHRA"), the British equivalent of the FDA, to show the BHR's safety, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons. Specifically, Smith & Nephew represented in the letter that the MHRA observed that:

a. There is no evidence for any association between hip replacements and an increased incidence of any malignant disease;

b. There is no evidence that the genotoxic effects seen in patients with metal-on-metal hip replacements are associated with increased levels of cobalt and chromium ions;

c. There is no evidence that increased levels of cobalt and chromium ions are associated with any clinical effects;

d. The distribution of cobalt and chromium ions in the body is unclear, particularly to the extent to which they can cross the blood-brain barrier or placenta;

e. While there is evidence for an immunological component in some, rarely seen, responses to wear debris, the precise mechanisms of the effects observed are unknown;

f. There is limited evidence to show that chromosome abnormalities may also be associated with ceramic-on-ceramic hip replacements. No conclusions can be drawn from these findings at present

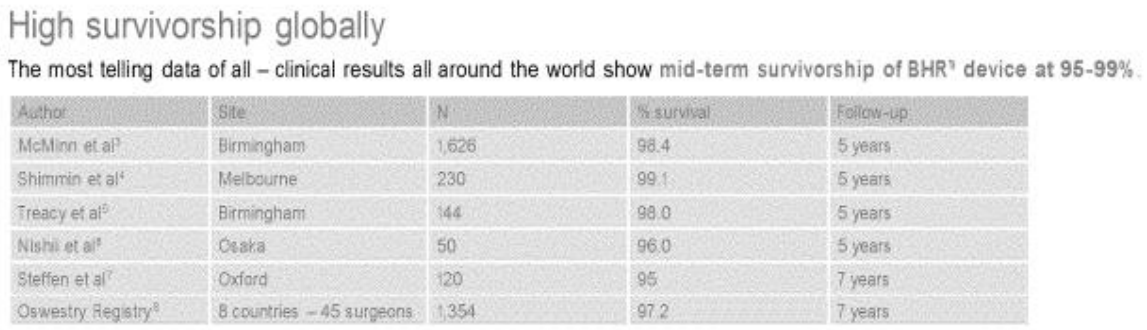
65. These false and misleading representations to physicians conveyed an explicit and implicit message: the BHR is safe despite its metal-on-metal makeup producing metal ions in patients' bodies. These representations were false and misleading when Smith & Nephew made them in 2008 and in 2010, and even more false and misleading as Smith & Nephew learned new information from those points until it recalled the BHR in 2015. Despite this, Smith & Nephew never updated physicians on the literature and research into the damage done by metal ions, nor did it update physicians on MHRA's position on metal-on-metal from 2011-2015. This failure to update left a false impression in surgeon's minds that no additional information about the safety of BHR, metal ions and metal-on-metal hips existed and therefore the BHR was still safe from 2011-2015.

66. These misrepresentations and failures to update the medical community caused Plaintiffs injuries.

67. Smith & Nephew was aware of subsequent MHRA guidance regarding monitoring metal ion levels in patients, and notified the FDA of this January 2011. Smith & Nephew delayed notification to the FDA by at least six months (the MHRA guidance was released in April 2010 and Smith & Nephew did not notify the FDA until January 2011) and, upon information and belief, asked the FDA to allow Smith & Nephew to change the post-approval study protocol as a result of this guidance so as to avoid having to communicate with surgeons, the medical community and patients. Had Smith & Nephew warned the medical community and Plaintiffs, instead of just the post-approval study participants, Plaintiffs would not have had the BHR implanted or would have received metal ion testing and monitoring as early as April 2010. Smith & Nephew's failure to do so was negligent, and was the proximate cause of Plaintiffs' injuries.

68. Smith & Nephew did not send this April 2010 MHRA guidance to surgeons in the form of Dear Doctor letters like it had the previous MHRA information.

69. Smith & Nephew represented to physicians that the BHR was safe through statistics and clinical studies, including the same studies it presented to patients:



High survivorship globally

The most telling data of all – clinical results all around the world show mid-term survivorship of BHR® device at 95-99%.

Author	Site	N	% survival	Follow-up
McMinn et al[3]	Birmingham	1,626	98.4	5 years
Shimmin et al[4]	Melbourne	230	99.1	5 years
Treacy et al[5]	Birmingham	144	98.0	5 years
Nishii et al[6]	Osaka	50	96.0	5 years
Steffen et al[7]	Oxford	120	95	7 years
Oswestry Registry[8]	8 countries – 45 surgeons	1,354	97.2	7 years

70. By including the results of these studies, but not including other studies or disclosing the truth about these studies, Smith & Nephew explicitly and implicitly misrepresented the safety of the BHR.

71. Smith & Nephew left the impression with surgeons and the medical community that the failure rate of the BHR was lower than it really was - and that the BHR was safe - by failing to provide updated studies and survivorship data from other sources, including S&N's own PMA-mandated studies.

72. Smith & Nephew ran advertisements in medical journals seen by surgeons in the United States, including the leading Journal of Bone and Joint Surgery ("JBJS") in 2010. This advertisement, like others to the medical community and directly to patients, included voluntary statements outside the FDA-approved labeling relating to the safety of the BHR.

73. The 2010 JBJS advertisement contained the following representations that were false, misleading and/or omitted material information:

a. "As you may have heard, some metal-on-metal implants have recently been withdrawn from the market due to poor clinical results. And some of the metal-on-metal implants that remain are falling short of the survivorship rates one would expect from one of the most effective surgical treatments in the history of medicine - total hip arthroplasty. The bottom line is that the poor results of a few have painted a negative picture of all metal on metal devices. **But the BHR® hip is not your average metal on metal device; it's BHR!**

b. In the Australian Orthopaedic Association's 2009 Joint Registry, a database of orthopaedic devices implanted in Australia, the BHR hip accounts for the most hip resurfacing implantations (N=8,427) and the **best results, with a 95% cumulative survivorship rate at eight years.**

c. In a report by the Oswestry Outcomes Centre Registry, a combination of results of 18 surgeons in 16 countries… The same registry showed greater than 95% survivorship at 10 years.

d. A recently published study in JBJS tracked 155 consecutive BHR patients over three years. The data showed **no revisions of BHR hips due to metal wear.** Patients who received a competing metal-on-metal resurfacing device were revised within three years of surgery at a rate of 3.4-percent due to adverse tissue reactions."

74. These representations explicitly and implicitly distinguished BHR from other metal-on-metal devices, dangerously downplayed the risk of metal ions to patients, and specifically represented to the medical community that the BHR was safe in statements that went beyond the FDA-approved warning label.

75. Smith & Nephew did not update the medical community about new findings in the literature and clinical studies, including literature authored by those Smith & Nephew specifically cited in the JBJS advertisements.

76. By including the results of these studies, but not including other studies or disclosing the truth about these studies, Smith & Nephew explicitly and implicitly misrepresented the safety of the BHR.

77. By including the results of these studies but not differentiating between male and female patients in the studies, or among the various head sizes, Smith & Nephew concealed the true failure rate of the BHR for women and patients receiving smaller head sizes.

78. Smith & Nephew left the impression with surgeons and the medical community that the failure rate of the BHR was lower than it really was - and that the BHR was safe - by failing to provide updated studies and survivorship, including S&N's own PMA-mandated studies.

79. Smith & Nephew's bold-faced assertion that data showed that no BHR revisions occurred due to metal wear was a bald-faced lie, and when Smith & Nephew learned that metal wear was causing revisions to patients with BHR devices, it concealed this information from the medical community and/or did not update the medical community, leaving the impression that the BHR would not fail because of metal wear rates. The author of the study Smith & Nephew cited, Langton, published numerous studies thereafter which showed both revisions of BHR hips due to metal wear, but also included specific warnings about the dangers of metal ions.

80. These misrepresentations caused Plaintiffs' injuries, as set forth in greater detail in their individual complaints pursuant to Case Management Orders in this MDL.

81. Smith & Nephew represented to the medical community and to patients that the BHR was safe by failing to warn of the high learning curve for surgeons and its reliance on inventor-surgeon data.

82. Specifically, Smith & Nephew was repeatedly criticized by researchers who found that early safety statistics for the BHR device could not be duplicated by outside surgeons who did not receive the detailed training of the original designers and surgeons.

83. In 2010, the JBJS published an article by Langton, et al., called Adverse Reaction to Metal Debris Following Hip Resurfacing, which found "overwhelming evidence to show that surgeons cannot consistently position the acetabular components precisely. Without exception, studies show wide variations in the angles of inclination of the acetabular component and, to an even greater extent, its anteversion."

84. Smith & Nephew presented data from McMinn and Treacy as two of the main sources showing high survival rates at 5 years. However, Smith & Nephew did not disclose that McMinn was the creator and inventor, and paid designer and promoter of the BHR and that he was Treacy's mentor, and that Treacy helped him develop the BHR. This material information would have indicated to surgeons that this data would not be replicated in the "real world" with less experienced surgeons who lacked the financial bias of McMinn and Treacy.

85. McMinn has described the learning curve of implanting the BHR as 1,000 surgeries. This material information was never disclosed by Smith & Nephew.

86. Smith & Nephew's failure to complete its PMA-mandated surgeon training and surgeon training studies compounded these misrepresentations, further misleading the medical community about the safety of the BHR.

87. In a 2012 article in International Orthopaedics (Schuh, R., D. Neumann, et. al., *Revision Rate of Birmingham Hip Resurfacing Arthroplasty: Comparison of Published Literature and Arthroplasty Registere Data*, Int. Orthop 36(7): 1349-1354), researchers found that the revision rate for the BHR was nearly three times higher for the general patient population than it was for patients treated by the original surgeons in England including Dr. McMinn who designed the BHR (0.27 revisions per 100 observed component years for development team, compared to 0.74 in national registry data). The study authors noted that "the excellent results reported by the development team are not reproducible by other surgeons."

88. A second study published in 2012 (J.P. Holland, et. al., Ten-year clinical, Radiological and Metal Ion Analysis of the Birmingham Hip Resurfacing, J. Bone & Joint Surg., 2012; 94-B 471-6) was even more critical, showing that a single surgeon not involved in designing the BHR device experienced a failure rate of 15.4 percent for female patients, and 44.4 percent for all patients with a 42 mm femoral head.

89. Finally, a third study published in 2012 (Reito, et. al., Results of Metal-on-Metal Hip Resurfacing in Patients 40 Years Old and Younger, Arch. Orthop. Trauma Surg) found that seven out of eight revision surgeries in resurfacing patients were due to adverse reaction to metal debris, and that "… overall survival was unsatisfactory."

90. Smith & Nephew did not provide these studies to the FDA, medical community, patients and Plaintiffs despite having previously provided the studies these articles and studies criticized and relying on those studies as proof that the BHR was safe.

91. The disparity in revision rates between these groups of patients is due in part to the way Dr. McMinn and Smith & Nephew reported failure rates for the first 2,385 patients implanted with the BHR system.

92. The clinical study of this group, called the Overall McMinn Cohort, did not track all 2,385 patients for key symptoms such as "patient satisfaction" or "pain and function." It also failed to include radiographic data for 2,261 of the patients, or 95 percent of the group. Additionally, no data was available on more than half of the patients due to lack of follow-up exams, refusal to participate in the study, death, or a lack of data five years after implantation. Of the individuals listed in the Overall McMinn Cohort, only 786 patients, or 33 percent, were implanted with a femoral head size 46 mm or smaller that fit within the parameters of the recall.

93. Finally, the patients in the Overall McMinn Cohort were not examined for classic signs of metal-on-metal failure such as pseudotumor, elevated levels of cobalt and chromium, adverse reaction to metal debris and tissue inflammation in the hip joint. Instead, patients who reported severe pain in their hips or clicking and grinding of the components were told to "take it gently" for a few weeks, or to go swimming to build up their muscles. Even those patients who underwent a revision surgery of their BHR system were described in the study as simply having "migration" of the device, despite evidence of cysts in their hip joints, or infections that suddenly appeared three or four years after implantation.

94. All of Smith & Nephew's representations and voluntary statements to the medical community outside the FDA-approved labeling omitted material facts known to Smith & Nephew at the time of the misrepresentations, and/or that should have been known to Smith & Nephew at the time of the misrepresentations, and/or that Smith & Nephew later learned but neglected to update, inform or correct the previous misrepresentations, including, but not limited to:

a. The BHR was not safe.

b. Metal-on-metal hips are unsafe regardless of the different features among them.

c. Metal-on-metal hips are not as safe as ceramic hip products.

d. Failure rates in women and in patients with smaller head sizes were much higher than in men and other patients, and the overall failure rates were actually higher than those reported by Smith & Nephew.

e. The inclusion of men, women and all head sizes in failure rates masked the true failure rates among women and patients with smaller head sizes;

f. The studies that Smith & Nephew represented as proof the BHR was safe were done by McMinn and Treacy, both of whom were the surgeons who designed, developed and sold the BHR to Smith & Nephew, and that McMinn believed that the learning curve for the BHR was more than 1,000 surgeries. Therefore, these survivorship numbers were misleading and could not be replicated in the real world.

g. That metal ions in any amount were harmful to patients.

h. That there was no evidence that patients had hypersensitivity to metal ions and that it made them more likely to need revision, nor any evidence that it was patients' fault that their hip products produced metal debris.

i. That metal ions produced by the BHR were higher than were naturally found in the body.

j. That an adverse reaction to metal debris causing the need for revision might take longer than 5 years, making the data about 5-year survivorship incomplete and irrelevant to the safety of the device.

k. That McMinn's studies lost track of numerous patients after 5-years when failure rates are more likely to go up.

l. That real-world failure rates were higher than early clinical studies on which Smith & Nephew relied.

m. That revision of a resurfacing product was worse for the patient than a total hip revision, that revision of a resurfacing product required the conversion to a total hip revision, and that the BHR was not approved in the United States for use in a total hip, which means that the surgeon would have to take out *all* of the BHR components, even if they were fully fixed and attached to the patient's body.

n. Smith & Nephew represented that the BHR components were of a particular standard, quality and/or grade, and they were not.

o. Smith & Nephew engaged in false and misleading conduct that led surgeons and the medical community to believe and understand that the subject components were safe, effective, permitted and intended to be used with one another when they were not and with the knowledge that the use of the subject components together would lead to serious injury and/or harm to patients in which they were used.

95. As a result of these misrepresentations, Plaintiffs suffered injuries, including receiving a BHR implant instead of a safer alternative, and delaying the removal of the BHR so as to cause additional damages.

96. These advertisements and marketing materials are alleged and included by way of example, and are not the full extent of outside-the-labeling representations made by Smith & Nephew to the medical community. Additional discovery most likely will produce additional marketing materials and the details of the marketing campaign, including that as carried out by sales representatives, for trial.

97. In sum, Smith & Nephew made numerous misrepresentations outside the FDA-approved labeling that caused Plaintiffs' injuries and for which Plaintiffs bring non-preempted state law claims.

C. Smith & Nephew Knew That the BHR was not as safe as it communicated To the Medical Community and Omitted Material Facts about Its Safety

98. Smith & Nephew made these representations about the safety of the BHR despite knowing, or despite the fact that it should have known, that the BHR was not safe, especially for women and patients receiving the smaller head size implants. Smith & Nephew knew about the safety problems in these patient populations for years before it finally issued a recall.

99. Smith & Nephew was aware of information about the BHR's unreasonably high risk of premature failure for certain patient populations as early as 2007, when the Australian Orthopaedic Registry published data from September 1999 to December 2006 showing that female resurfacing patients had a two-fold increase of revision at three years compared to men, and a nearly three-fold increased risk of revision at five years. The following year, in 2008, the Australian registry gave additional warnings, stating in its annual report that women with a femoral head size of less than 50 mm faced a more than three-fold increased risk of revision (Hazard Rate "HR" = 3.22, at 95 percent confidence interval) compared to female patients with a larger head size. Similarly, men with a femoral head size of less than 50 mm faced a far higher risk of revision compared to other male patients with a larger head size (HR = 2.69, at 95 percent confidence interval).

100. Two years after the publication of the Australian joint registry data, one of Smith & Nephew's own paid researchers, Callum W. McBryde, performed a study showing a more than four-fold increased risk of failure (HR = 4.68 times higher) for each 4-mm decrease in the size of the BHR patient's femoral head. McBryde wrote in a 2010 article that the increased risk of revision was unrelated to surgeon technique, and that femoral head size was the best indicator of revision rate.

101. A February 2012 article in the Journal of Bone and Joint Surgery by D.W. Murray, et. al., revealed the BHR has a 26 percent failure rate in women after ten years, and the authors of the article warned that "results in women have been poor and we do not recommend metal-on-metal resurfacing in women." Smith & Nephew did not communicate this article to the medical community or patients and Plaintiffs despite having previously communicated studies and medical journal articles touting the BHR's supposed safety and low failure rates. The industry benchmark failure rate for a hip device is no more than 5.0 percent at ten years.

102. On September 10, 2015, Smith & Nephew issued a Class 2 recall of the BHR device covering 5,987 units (Recall Number Z-2745-2015), 10,167 units (Recall Number Z-2746-2015) and 624 units (Recall Number Z-2747-2015) in the stream of commerce due to "revision rates which were higher than established benchmarks." Defendant knew, and continues to know, that its disclosures to the public and Plaintiffs were and are incomplete and misleading; and that Defendant's BHR resurfacing products were and are causing numerous patients severe injuries and complications. Smith & Nephew suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

103. At all relevant times, Defendant knew or should have known that the relative safety of metal-on-metal devices was a misleading representation. Smith & Nephew was aware of problems with metal-on-metal hips generally when it sent a team of employees and/or consultants, including Tim Band, Dr. Joseph Daniel and BHR inventor Dr. Derek McMinn, to participate in the FDA's Orthopaedic and Rehabilitation Devices Advisory Panel meeting on metal-on-metal hip implant systems on or about June 27-28, 2012, in Gaithersburg, Maryland. The purpose of the meeting was to discuss mounting concerns about the safety of metal-on-metal hip devices, both

for total hip arthroplasty and hip resurfacing arthroplasty. It followed an FDA statement in February 2011 about health risks of metal-on-metal systems for both types of procedures.

104. At all times relevant Smith & Nephew knew or should have known that its survivorship data was misleading and incomplete, as real-world survivorship data was lower than what Smith & Nephew presented to the medical community and to patients. Survivorship is the inverse of failure, or revision.

105. For example, data published in connection with the recall show a total of 397 "device problems" with the BHR, including numerous safety problems related to "metal shedding debris" and other symptoms typical of metal-on-metal device failure. Earlier, in its 2012 post-marketing annual report to the FDA, Smith & Nephew disclosed 356 reportable complaints for the BHR alone between March 1, 2011, and February 29, 2012. However, this data does not include at least an additional thirty (30) reported complaints during the same time period, or 8.4 percent more complaints than Smith & Nephew disclosed in its annual report. Numerous complaints also were not logged with the FDA until six months or longer after Smith & Nephew received them, and in some cases they were not logged until several years later.

106. The following year, Smith & Nephew disclosed 380 reportable complaints between April 1, 2012, and April 1, 2013. But Smith & Nephew failed to accurately report, or conduct follow-up investigations, for more than half of these safety problems to the FDA. For example, it stated "no code available" for 64 of the incidents, and stated "no information" for another 153 incidents, even though many incidents were reported by attorneys, physicians and other parties who easily could have provided additional details.

107. By this time, 2013 and 2014, Smith & Nephew did state that at least some of the revision surgeries were due to metallosis. However, in the first several years after the BHR entered

the U.S. market, Smith & Nephew failed to report the risk of metallosis in its adverse events to the FDA. According to an independent analysis of these adverse event reports, the term "metallosis" was not used in these reports until late 2010, even though the company knew of dozens and possibly hundreds of cases where metallosis was found. Instead, Smith & Nephew went to great lengths to blame device failure on other sources, such as the patient's allergies to metal, or generalized pain. A short list of examples demonstrating how Smith & Nephew avoided responsibility for the BHR's metal-on-metal risks:

a. Adverse Event Report 1921214 (2010): "the revision surgeon does not fault the devices"

b. Report 1058217 (2008): "it was reported that revision surgery was performed due to metal allergy."

c. Report 1353825 (2009): "incorrect positioning"

d. Report 1402939 (2009): "revision surgeon does not fault the device."

e. Report 960061 (2007): "surgical error"

f. Report 1626209 (2010): "nickel allergy"

108. While Smith & Nephew tried to hide the true cause of the BHR's failure rate, clinical data continued to pile up showing the real risk for patients including Plaintiffs. Data compiled by the National Joint Registry of England and Wales, for example, show the BHR 42 mm femoral head component has a seven-year revision rate of 11.76 percent, well above the normal acceptable benchmark failure rate for a device of this type.

109. A separate study of the BHR device in England showed that out of 319 patients, nearly 30 percent had modified Harris Hip Scores below 90 at their ten-year follow up exam, and

approximately 12 percent of patients had scores below 80. A score above 90 is considered excellent. Scores below that number are described as either poor, fair, or good.

110. The failure to timely report these adverse events harmed Plaintiffs and is the proximate cause of their injuries. Had S&N timely and accurately reported adverse events, Plaintiffs' surgeons would have known the truth about the BHR long before the 2015 recall, and Plaintiffs would have not received the BHR implant or would have had it revised sooner.

111. Because the BHR fails in part due to metal wear and debris, and metal wear and debris builds up over a period of years, there is an increased risk of failure 5 or more years after implantation of the device. Smith & Nephew reported 5-year survivorship rates and failed to inform the medical community, Plaintiffs and patients that this data was misleading and was not a true indicator of the long-term safety of the BHR.

112. This data was also false and misleading in that many studies on which it was based had huge decreases in follow up after 5 years, and were done by inventing surgeons McMinn and Treacy and therefore were not indicative of real world performance.

113. Smith & Nephew knew or should have known that failing to continue to provide updates from medical authorities concerning the safety of the BHR device would mislead the medical community and patients.

114. Smith & Nephew knew or should have known that most surgeons were not adequately experienced to implant the BHR safely and the reliance on inventor-surgeon data was false and misleading, would likely mislead surgeons and in fact did mislead Plaintiffs' surgeons.

115. As a direct result of Smith & Nephew's many misrepresentations, failures to update the medical community, omissions and acts described above, Plaintiffs were injured.

III. Smith & Nephew Continued Selling Metal Hips Despite Industry-Wide Failure

116. Despite Smith & Nephew's knowledge of the failure rate of its own devices, and other metal-on-metal hip prostheses, it continued to sell the BHR. Alarmingly, Smith & Nephew continued selling metal-on-metal hips long after its competitors' metal-on-metal hips were recalled and removed from the market.

A. MOM As a Device Class Was Shown to Be Unsafe Long Before Smith & Nephew Recalled the BHR

117. The Committee on Safety of Devices (now, the Devices Expert Advisory Committee, DEAC) is responsible for providing independent expert input and advice on medical devices to the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA) to aid the MHRA in its role in ensuring the safety introduction and management of medical devices to the population. In October 2006, the minutes from the first Expert Advisory Group (EAG) established by the Committee on Safety of Devices, note that wear debris can be generated from articulating surfaces, specifically metal-on-metal couples, and that as of 2006, there has been a growing concern about the biological effects of metal wear debris generated from hip replacement implants.

118. In 2007, analysis by the Australian Register of Therapeutic Goods (ARTG) of data reported by the Australian National Joint Replacement Registry suggested that the DePuy ASR resurfacing hip implant was associated with a higher than average replacement rate.

119. On January 2, 2008, the EAG issued a report containing advice on the biological effects of metal wear debris generated from hip implants. The report required all adverse incidents associated with metal-on-metal hip implants, including early revisions, and soft tissue reactions, be reported to the MHRA. The report further recommended research to determine the distribution of cobalt and chromium ions, and to characterize the potential adverse health effects that may

result from increased exposure to chromium and cobalt ions. Despite early advertising and communications to surgeons relying on the MHRA to show the BHR's safety, Smith & Nephew did not communicate this MHRA action, information or guidance to surgeons.

120. On July 22, 2008, Zimmer temporarily suspended distribution of its Zimmer Durom metal hip prosthesis under FDA pressure, after Dr. Lawrence Dorr, a former consultant of Zimmer, publicly warned American Association of Hip and Knee Surgeons colleagues about the large number of his patients experiencing failure of the Durom.

121. That same year, in 2008, the Australian registry gave additional warnings, stating in its annual report that women with a femoral head size of less than 50 mm faced a more than three-fold increased risk of revision (Hazard Rate "HR" = 3.22, at 95 percent confidence interval) compared to female patients with a larger head size.

122. Less than two years later, in March 2010, Johnson & Johnson acknowledged its DePuy ASR metal hip prosthesis had a higher-than-normal failure rate, despite months earlier claiming that it was phasing out the ASR due to declining sales.

123. On March 9, 2010, the EAG met again to review new information related to metal wear debris from hip implants. The meeting minutes state that the EAG reviewed new findings on the possible damage done to the body when it is exposed to metal ions across an intact cellular barrier. The EAG further accepted that the wide variation in patient symptoms does not always correlate directly with the patient's blood metal ion levels, prompting the EAG to update their previous report.

124. On April 22, 2010, the MHRA issued a medical device alert that included specific follow-up recommendations for patients with metal-on-metal hip replacements, including blood tests and imaging for patients with painful metal-on-metal hip implants. MDA 2010/033. Despite

early advertising and communications to surgeons relying on the MHRA to show the BHR's safety, Smith & Nephew did not communicate this MHRA action, information or guidance to surgeons.

125. On May 25, 2010, the MHRA issued a medical device alert advising physicians to ensure ASR hip prostheses are implanted according to the manufacturer's instructions, and to follow-up with patients that receive ASR prostheses. MDA 2010/044. Despite early advertising to surgeons relying on the MHRA to show the BHR's safety, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

126. Three months later, on August 24, 2010, DePuy recalled the ASR XL Acetabular metal-on-metal device.

127. In October 2010, the EAG released its updated report on soft tissue reactions associated with metal-on-metal hip replacements. The Report included advice for use of metal-on-metal hip replacements, noting that higher failure rates have been reported in females, and that all patients with metal-on-metal hip bearings should be followed up at least annually for five years post operatively and more frequently in the presence of symptoms. Despite early advertising to surgeons relying on the MHRA to show the BHR's safety, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

128. The October 2010 EAG Report further concluded that based on questionnaires sent to only those surgeons who had revised metal-on-metal implants: (i) soft tissue reactions occurred in 14.2% of revised metal-on-metal devices; (ii) an incident rate of 15% of the revised hip resurfacing arthroplasties; and (iii) an incident rate of 12.5% of the revised total hip resurfacings. The Report concluded: There is a need for more detailed information gathering to ascertain the reasons for revision of hip resurfacing devices. Despite early advertising to surgeons relying on

the MHRA to show the BHR's safety, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

129. On February 28, 2011, a study published in The Bone & Joint Journal (Matthies A, Underwood, R, Cann P, Ilo K, Nawaz Z, Skinner J, Hart AJ: Retrieval analysis of 240 metal-on-metal hip components, comparing modular total hip replacement with hip resurfacing. J Bone Joint Surg Br. 2010, 93: 307-314) compared failed metal-on-metal hip resurfacing and modular total hip replacements, finding they have the same wear rates and both types of devices are associated with increased blood levels of metal ions.

130. In February 2011 the FDA launched a metal-on-metal hip implant webpage, providing updated safety information and recommendations for patients and healthcare providers, including responding to localized symptoms, recommendations for metal ion testing, and information concerning joint revision.

131. On May 6, 2011, the FDA ordered all manufacturers of metal-on-metal devices to perform post-market surveillance studies, requiring manufacturers to examine adverse events as well as patients' pre- and post-implantation levels of cobalt and chromium. The alert required manufacturers to study the effects of metal ion concentrations in the bloodstream.

132. On February 28, 2012, the MHRA issued a medical device alert recommending annual patient follow-up for not less than five years, MARS MRI testing, as well as initial and follow-up blood metal ion testing. MDA 2012/008. Despite early advertising and communications to surgeons relying on the MHRA to show the BHR's safety, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

133. On May 9, 2012, Health Canada issued a public health communication to all orthopedic surgeons and patients concerning management and follow-up for patients implanted with a metal-on-metal hip device.

134. On June 25, 2012, MHRA updated its previous medical device alert, including updated advice on follow-up recommendations for metal-on-metal hip resurfacing patients. The alert recommended patient follow-up annually for the life of the implant in patients that received a resurfacing product, as well as MARS MRI or ultrasound imaging, and at least one blood metal ion test. Despite early advertising and communications to surgeons relying on the MHRA to show the BHR's safety, Smith & Nephew did not communicate this new MHRA action, information or guidance to surgeons.

135. In June 2012, the FDA convened the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee seeking scientific and clinical expert opinions on the risks of metal-on-metal hip systems.

136. The next month, July 2012, Stryker issued a Class 2 recall of its ABG II and Rejuvenate metal-on-metal hip systems due to revisions associated with fretting and corrosion of the metal device.

137. On October 3, 2012, cases against Biomet, Inc. and various co-defendants concerning its defective metal-on-metal hip implants were consolidated for multidistrict litigation in Indiana.

138. Despite the unquestionable danger of metal-on-metal hips at this time, in 2012, Smith & Nephew's Senior Vice President continued to publicly state that the BHR was "unlike any other metal-on-metal hip implant" in an effort to distinguish the BHR from its failing

competitors. This representation was not true, and in fact, the BHR had similar or even higher failure rates than other metal-on-metal devices.

139. On January 17, 2013, the FDA issued a safety communication to orthopedic surgeons, healthcare providers, and patients, stating there are unique risks associated with metal-on-metal implants in addition to the general risks of all hip implants. The safety communication further explained that metal release from the articulation of the components can cause damage to bone and tissue causing pain, implant loosening, device failure and the need for revision surgery. *See* https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm335775.htm

140. The following day, January 18, 2013, the FDA published proposed rules requiring all manufacturers of metal-on-metal hips to establish the safety of their devices, even those already marketed.

141. On November 19, 2013, the first settlement in the DePuy ASR metal-on-metal hip MDL was announced. To date more than 25,000 lawsuits involving metal-on-metal hip implants have been filed in federal courts.

142. A 2013 study looked at 143 BHR hips and found pseudotumors in 28 percent of all patients, regardless of gender, less than four years of implant. R. Bisschop, et al., *High Prevalence of Pseudotumors in Patients with a Birmingham Hip Resurfacing Prosthesis,* J. Bone Joint Surg. Am. (2013) 4;95(17).

143. Another 2013 study sought to determine whether elevated blood cobalt concentrations were associated with early failure of metal-on-metal hip resurfacings secondary to adverse reaction to metal debris (ARMD) by comparing the DePuy ASR and Smith & Nephew's BHR. The results revealed blood cobalt concentration was a positive and significant risk factor for joint failure. Langton DJ, Sidaginamale RP, Joyce TJ, et al. The clinical implications of elevated

blood metal ion concentrations in symptomatic patients with MoM hip resurfacings: a cohort study. *BMJ Open* 2013; 3:e001541.

144. Despite the well-documented, public failure of metal-on-metal hip prosthesis, Smith & Nephew continued to not only sell its metal-on-metal BHR, but to attempt to distinguish it from the failed products of DePuy, Zimmer, and Biomet. It was not until September 2015 that Smith & Nephew recalled the BHR.

145. On February 18, 2016, the FDA issued a final order requiring manufacturers to submit premarket approval (PMA) on or before May 18, 2016 for two types of metal-on-metal hip systems.

146. Smith & Nephew knew that MOM devices were unsafe, and the explicit and implicit message of its slogan "BHR is not your average 'metal on metal.'" was that metal on metal hips were unsafe, but the BHR was somehow different. In fact, BHR *was* the average metal on metal hip — a higher failure rate than some, a lower failure rate than other metal hips.

147. Once S&N communicated the actions of the MHRA to surgeons to represent that the BHR was safe, Smith and Nephew had a duty to update or to continue to communicate MHRA actions that implicated the safety of the BHR. Smith & Nephew failed to do so, causing or contributing to Plaintiffs' injuries.

148. Because Smith & Nephew expressly distinguished the safety of its product from other MOM devices through communications outside the labeling, Plaintiffs' surgeons and the medical community had a misimpression of the true safety of the BHR, and continued to implant it into Plaintiffs. Had Smith & Nephew complied with its duties of care and state statutory duties as defined below, Plaintiffs would not have been injured.

B. Derek McMinn Was the Face of Marketing and Safety for BHR, And His Public Statements, Ethical and Financial Conflicts of Interest, and Misleading Studies Are Further Violations of the PMA

149. Derek McMinn was the paid face of marketing and safety for the BHR, and his misleading or false public statements and misleading studies are further violations of the PMA and/or were made outside the FDA-approved labeling and therefore constitute evidence of violations of state law that are not preempted.

150. McMinn developed and pioneered the BHR, and took it to market in the U.K. in 1997 through his own company, Midland Medical Technologies (MMT). The BHR was developed in his garden shed.

151. On information and belief, McMinn focused on developing a presence for the BHR system in the United States. MMT (and McMinn) then sold the BHR System to Smith & Nephew in 2003 for 67 million pounds, the equivalent of $88 million in the U.S. McMinn then served as a consultant orthopedic surgeon to Smith & Nephew from at least 2004 to 2009, and likely consecutively to the present. On information and belief, Dr. McMinn also served as an expert for Smith & Nephew well into 2016. He personally trained numerous surgeons in how to implant the BHR, and he served as the author of numerous versions of the BHR's surgical technique guide and other important documents.

152. Along with McMinn, Smith & Nephew enlisted the services of professional athletes and celebrities in its efforts to promote the BHR system, including former NHL hockey player Tim Taylor, former NFL quarterback Steve Beuerlein, and former professional cyclist Floyd Landis. The most recent example of these misleading marketing efforts is a campaign by McMinn himself, modeled after the presidential campaign slogan of Donald Trump, to "Make Resurfacing Great Again," through the use of a safer resurfacing device that includes a polyethylene acetabular cup,

the PHR, which purportedly avoids the problems associated with metal-on-metal articulation in the original BHR system. McMinn explicitly states: "Together, this metal-on-polyethylene articulation is an ideal solution for patients, particularly women, who have an allergy to metals."

153. Thus, despite an overwhelming body of clinical literature showing the dangers of cobalt and chromium toxicity, the BHR's inventor and paid spokesman continues even today to blame patient "allergy sufferers," rather than the manufacturer or himself, for widespread metal-on-metal injuries. Dr. McMinn also is calling on Smith & Nephew to reverse the recall for women and patients with smaller joint sizes, claiming in an online petition that Smith & Nephew failed to consult with him before issuing the recall through the website change.org. McMinn's petition asks Smith & Nephew to put the recalled device back on the U.S. market but only make it available to surgeons such as himself instead of American doctors, some of whom he calls "trainee surgeons."

154. The PMA for the BHR System was based solely upon studies developed and submitted by McMinn, many of which were later questioned or discredited due to bias and poor patient follow-up rates. For example, during the FDA meeting of the Orthopedic and Rehabilitation Devices Panel on September 8, 2005, in regard to the PMA approval of the BHR, Dr. William Maloney, III, Professor and Chairman of Orthopedics at Stanford University School of Medicine noted: "In the McMinn cohort, it appears to have no functional outcome data. It is specifically just survivor data, as the outcome data was not available for review of this submission, and it doesn't appear that those patients in the McMinn cohort were actually consented for a research study."

155. On information and belief, upon Smith & Nephew's acquisition of Midland and the BHR System, Defendant was aware of the defective manufacture and significant issues associated with the BHR. Defendant was also aware of the problems with the studies submitted to the FDA

as part of the PMA process, which were also separately communicated to medical professionals and patients, including Plaintiffs, outside the labeling.

156. Among other affirmative false representations made on behalf of himself, Smith & Nephew, and the BHR System, McMinn represented repeatedly though various media outlets and/or his website hipresurfacingsite.com that:

a. All of his surgeries have a low risk of complications;

b. Metallosis does not result from implantation of the BHR system, the fear of ions is not legitimate and any injuries are a result of poor implantations. Mr. McMinn has gone on to represent that "[v]ery early after the introduction of the BHR [McMinn] compared the cobalt levels of highly active patients who had had BHRs with the cobalt levels in patients who had historic cobalt-based metal-on-metal hip replacements performed 19 to 30 years before and found that the levels in these two groups were in the same range. Therefore we can expect with good reason that the BHRs will follow the progress of these historic devices."

c. There is a 96% survivorship rate amongst all patients with all diagnoses who are implanted with the BHR system;

d. Heavy impact sports will have no impact upon the implant, and that he does not place any restrictions upon his patients upon having an implantation;

e. He personally implanted 3500 BHR devices and has only had one patient who experienced a pseudotumor; and

f. Irrespective of age or diagnosis, male patients have a 98% chance of survival at 10 years, and female patients have a 96% chance of survival.

157. McMinn even suggested that any metallosis symptoms suffered by patients subsequent to the implantation of the BHR system may be caused by women wearing costume jewelry for an extended period in multiple outlets, lectures and on his own website.

158. McMinn's actions and financial compensation from Smith & Nephew also violated the Sept. 27, 2007, Deferred Prosecution Agreement ("DPA") between Smith & Nephew and the U.S. Attorney's office for conspiracy to violate the federal anti-kickback statute from 2002 through 2006. A key part of the DPA involved the establishment of an effective corporate compliance

program with a mandate to adhere to the AdvaMed Code of Ethics on Interactions with Health Care Professionals. Those AdvaMed principles were expressly incorporated as compliance requirements under the DPA. Interactions between the company and health care professionals must adhere to the following ethical codes:

a. Consulting agreements must be in writing and describe all services to be rendered.

b. If clinical research is done there must also be a written research protocol.

c. Consulting agreements should be entered only when there is a legitimate need for the services identified in advance and documented.

d. Royalties paid to physician in exchange for intellectual property should not be conditioned on a requirement the physician order or recommend a product or a requirement to market the product. Royalties that tie profit to number of units sold would be suspect for violating the ethical code.

e. Research support, grants, and lease agreements must follow principles of necessity, transparency and written criteria similar to consulting agreements.

159. The misleading and biased nature of McMinn's studies and lack of scientifically sound research protocol working in concert with his compensation from Smith & Nephew is a blatant disregard of the AdvaMed Code of Ethics and a deviation from the terms of the DPA and the PMA.

IV. Smith & Nephew Failed To Comply With Terms of PMA

A. Preemption Under The MDA

160. Manufacturers of Class III devices such as the BHR are required to obtain premarket approval ("PMA") from the Food and Drug Administration before they can make their products available to patients. 21 U.S.C. § 360(e). The PMA process is part of the regulatory

framework of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1976.

161. The duties of a Class III medical device manufacturer do not end with PMA approval. Instead, the MDA imposes a number of ongoing requirements, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order pursuant to 21 C.F.R. § 814.80, and to conduct ongoing safety studies and notify the FDA of any unexpected serious problems with the device.

162. A U.S. manufacturer of Class III medical devices with PMA approval must comply with the FDA's Quality Systems Regulations ("QSR"). 21 CFR § 820 *et seq*. The specific QSR promulgated by the FDA are known as Current Good Manufacturing Practices ("CGMP"). 21 CFR § 820.1(a). A manufacturer must satisfy these quality standards in the manufacture and production of medical devices. 21 CFR § 820.1(a).

163. The purpose of the CGMP requirements is to govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. 21 C.F.R. § 820.1(a)(1). To comply with CGMP requirements, a device manufacturer must adopt a variety of procedures and controls relating to areas such as: (1) design control, (2) quality assurance, (3) manufacturing and processing, (4) process validation, (5) device inspection, and (6) corrective and preventive action. 21 C.F.R. §§ 820.1–.250).

164. These quality standards include the duty to identify and respond to a "nonconforming product." A manufacturer, such as Smith & Nephew, must "establish and maintain procedures to control product that does not conform to specified requirements," such as

a failure to conform to performance and design standards set forth in the manufacturer's PMAs and supplements. 21 CFR § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSR also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21 CFR § 820.100.

165. FDA's CGMP/QSR may require a manufacturer to test for, monitor for (through post-marketing surveillance), discover, investigate and remedy issues related to the safe and effective use of a medical device as approved. A part of satisfying these post-marketing surveillance duties can be to formulate and then effectively execute a Postmarketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 CFR § 822.8.

166. Similar to Postmarketing Surveillance Plans, CGMP/QSR require a manufacturer to review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 CFR § 820.198(b).

167. An investigation must be completed when a complaint involves the possible failure of a device, its labeling or its packaging to meet any of its specifications, unless an investigation for a similar complaint has already been performed. 21 CFR § 820.198(c).

168. Also similar to Postmarketing Surveillance Plans, a device manufacturer is required to establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless

the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 CFR § 820.250 and 21 CFR § 820.1(a)(3).

169. A medical device manufacturer is required to comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device.

170. In particular, a manufacturer must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21 U.S.C. § 360i. "Serious injury" is defined to mean an injury that "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure…." *Id.*

171. According to its Congressional mandate, the FDA must establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360i.

172. Adverse events associated with a medical device must be reported to the FDA within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction was to recur. 21 CFR § 803.50(a).

173. This reporting is mandatory and is a condition of continued PMA approval. 21 CFR § 814.82. Such reports must contain all information reasonably known to a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 CFR § 803.50(b)(1).

174. In addition, a manufacturer is responsible for conducting an investigation of each adverse event and must evaluate the cause of the adverse event. 21 CFR § 803.50(b)(3). A manufacturer must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event and whether the remedial action was reported to the FDA as a removal or correction of the device. 21 CFR § 803.52(f), (9).

175. A manufacturer must report to the FDA in five (5) business days after becoming aware of any Medical Device Report ("MDR") event or events, including a trend analysis, which necessitates remedial action to prevent an unreasonable risk of substantial harm to public health. 21 CFR § 803.53.

176. This reporting is mandatory and a condition for continued PMA approval. A device manufacturer must report promptly to the FDA any device corrections and removals, and maintain records of device corrections and removals. 21 CFR § 806.10(a). FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by a manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the FDCA caused by the device which may present a risk to health. 21 CFR § 806.10(b).

177. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. A manufacturer must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal and provide a copy of all communications regarding the correction or removal. 21 CFR § 806.10(c).

178. FDA regulations state: "Recall means a firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." 21 CFR § 7.3(g).

179. A Recall does not necessarily mean a removal of a marketed device, but may also include its "correction" by "repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location." 21 CFR § 7.3(h).

180. A device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with the federal requirements. 21 U.S.C. § 351(e) & (h).

181. Devices subject to an FDA recall are, by definition, adulterated and prohibited for introduction into interstate commerce by the Federal Food, Drug, and Cosmetic Act ("FDCA"). 21 U.S.C. § 331(a).

B. Smith & Nephew's Duties Under the MDA

182. Manufacturers of Class III devices such as the BHR are required to obtain PMA approval from the FDA before they can make their products available to patients. 21 U.S.C. 360(e). The PMA process is part of the regulatory framework of the Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1976.

183. The duties of a Class III medical device manufacturer do not end with PMA approval. Instead, the MDA imposes a number of ongoing requirements, including requiring manufacturers to strictly adhere to the design, manufacturing, packaging, storage, labeling, distribution, and advertising specifications in the PMA approval order pursuant to 21 C.F.R. 814.8,

and to conduct ongoing safety studies and notify the FDA of any unexpected serious problems with the device.

184. As stated in Smith & Nephew's PMA Approval Letter for its BHR device: "… [T]he manufacturer shall submit the appropriate reports required by the MDR Regulation within the time frames as identified in 21 CFR 803.10(c) … i.e., 30 days after becoming aware of a reportable death, serious injury, or malfunction as described in 21 CFR 803.50 and 21 CFR 803.52 and 5 days after becoming aware that a reportable MDR event requires remedial action to prevent an unreasonable risk of substantial harm to the public health."

185. Thus, unexpected adverse events or expected adverse events in more frequency than that expected in the original PMA approval and/or any device issue that requires changes in labeling, manufacturing processes or device design are not sanctioned by the FDA in its original approvals, and are subject to further review and action by the agency despite such original approvals.

186. A manufacturer marketing a medical device in the United States under an approved PMA must submit for approval by the FDA a PMA Supplement when proposing any change to the device that affects its safety and effectiveness, including any new indications for use of a device, labeling changes, or changes in the performance or design specifications, circuits, components, ingredients, principle of operation or physical layout of the device. 21 CFR § 814.39(a).

187. A failure to comply with the conditions of PMA approval (especially including violation of FDA Regulations described above) invalidates PMA approval orders.

188. Commercial distribution of a device that is not in compliance with these conditions is a violation of the FDCA.

189. Congress anticipated that a manufacturer tasked with post-market surveillance of its PMA approved product's performance, such as the BHR, would require a voluntary mechanism to be able to quickly update its approved product's manufacturing, labeling and marketing to protect the public and to ensure its own compliance with the Act. Such a mechanism, to be expedient, protect patients and comply with the FDCA, should not be delayed because the FDA has not yet given its formal approval.

190. A manufacturer of an approved PMA may voluntarily implement certain changes to its device, its manufacturing processes or its labeling to enhance the safety of the device prior to obtaining FDA approval.

191. Such changes need not wait for FDA approval but can be implemented immediately. These changes may include, but are not limited to, labeling changes that add or strengthen a contraindication, warning precaution, information about an adverse reaction or information intended to enhance safe use, or changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provides additional assurance of purity, strength or reliability of the device. 21 CFR § 814.39(d)(1) and (2).

192. The PMA regulation (21 CFR § 814) sets forth general criteria for determining when a device manufacturer must submit a PMA supplement and details the various types of supplements available to the device manufacturer.

193. The MDA contains an express preemption provision found at 21 U.S.C. § 360k, so long as the manufacturer follows all of the conditions set forth in the PMA and in the MDA generally.

194. The MDA does not, however, preempt state law claims that are sufficiently parallel to a violation of the above federal requirements, so long as those claims are based on violations of state law duties that predate and operate independently from the federal requirements.

C. Smith & Nephew Received Premarket Approval for the BHR that Included Conditions, Conditions That Smith & Nephew Never Met

195. Nor should preemption under § 360k apply when, like here, Smith & Nephew did not ever meet the conditions set out in the PMA approval, and in fact recalled the device for women and patients with small head sizes.

196. In order to sell the metal-on-metal BHR in the U.S., Smith & Nephew submitted its first application for PMA to the FDA on or about July 19, 2004.

197. On May 9, 2006 the FDA completed review of Smith & Nephew's PMA application for the BHR, and based on the materials submitted by Defendant, the FDA conditionally approved the BHR for commercial distribution.

198. The Approval Order from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C. §§ 301, et seq.]."

199. The Approval Order cited many agreements Smith & Nephew made with the FDA, which became part of the approval. Thus, the Approval Order became an outline of the specific post-market obligations and duties Smith & Nephew undertook, in addition to all those existing under Federal Law, when it finally convinced the FDA to conditionally approve the BHR. Those agreements included, but were not limited to, the following:

a. Smith & Nephew would conduct a post-approval study and submit its reports biannually the first two years and annually for the next eight years following

premarket approval, which study was to evaluate the "longer-term safety and effectiveness" of the BHR;

b. Smith & Nephew would implement a training program of its physicians, which was to include quarterly investigator teleconferences or meeting the first two years "to discuss study issues including adverse events; and to identify recommendations for improvement of the training program or labeling";

c. Smith & Nephew would "provide an analysis of adverse events and complaints (including MDRs) received regarding the BHR system";

d. Smith & Nephew would advise of the results of its post-approval studies, training program assessment, and adverse event analysis through a supplement in its labeling upon completion of the post-approval study, or at "earlier timepoints, as needed."

200. The Approval Order made clear that each requirement imposed upon Smith & Nephew with respect to its distribution of the BHR system was to "ensure the safe and effective use of the device."

201. After Smith & Nephew received approval of the BHR system on May 9, 2006, Smith & Nephew became aware of defects in the BHR and harm it was causing, as well as deficiencies in surgeon training, but did not respond in accordance with its obligations, including but not limited to, the following:

a. Smith & Nephew received hundreds of adverse reports and complaints regarding the BHR but delayed its reporting to the FDA, and when it did communicate adverse reports, it did not do so properly but, in fact, attempted to blame others for the adverse events;

b. Smith & Nephew only initiated follow up inquiry on a fraction of adverse event reports by the patients' surgeons and sales force regarding the BHR;

c. Smith & Nephew became aware of widespread evidence that the BHR systems were wearing down more quickly and severely than anticipated, and failed to take appropriate action to determine the cause and provide a solution, nor did it appropriately advise the FDA;

d. Smith & Nephew, when it did provide reports to the FDA pursuant to the Approval Order, underreported to and withheld information from the FDA about the likelihood of failure; and/or,

e. Smith & Nephew also failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products and actively misleading the FDA, the medical community, patients, and public at large into believing that the BHR system was safe and effective.

202. Smith & Nephew's failures to follow the requirements of the Approval Order constitute violations of the Federal Food, Drug, and Cosmetic Act, pursuant to 21 CFR § 801.109 and furthermore voids any legal protection that Defendant enjoys from tort claims as part of the device's PMA status. Specifically, Smith & Nephew failed to warn healthcare professionals, the public, and Plaintiffs in particular, of the new information it learned about the BHR's risks, and failed to take reasonable efforts to issue an effective post-sale warning. PMA approval is not intended to offer blanket immunity, particularly where there are numerous, ongoing violations of the requirements of the Approval Order.

203. Smith & Nephew has not provided detailed discovery on many of the above topics, including surgeon training, adverse event reporting, manufacturing defects, and its failures with regard to the post-approval clinical study, which demonstrate how Smith & Nephew failed to comply with the PMA. For example, the clinical study required Smith & Nephew to recruit 350 patients in the United States who were implanted with the Birmingham system, and to follow them at regular intervals and perform exams with company-recruited surgeons. It also agreed to collect data from clinical exams, x-rays, and an annual questionnaire, and compile information on each patient's Harris Hip Score, including pain, function, movement, revision status and adverse events during a 10-year period following implantation. But at least one of the study surgeons dropped out of the Study, and others failed to notify patients of the health risks of metallosis, even after study subjects reported toxic levels of cobalt and chromium in their blood.

204. Smith & Nephew also failed to enroll the required number of patients in the study. For example, in May 2013, approximately seven years after PMA approval, the company told the FDA that it still had only enrolled 269 out of the planned 350 patients in the study. On information and belief, only a small fraction of the required number of patients were enrolled in the study during the first five years the BHR was available in the U.S., despite tens of thousands of the devices being sold and implanted in U.S. patients between 2006 and 2013, including more than 10,500 acetabular BHR cups in 2008 alone.

205. The clinical study in the U.S. was further delayed and hampered by allegations of criminal misconduct by Smith & Nephew, culminating in a Deferred Prosecution Agreement with the U.S. Attorney's Office for the District of New Jersey on Sept. 27, 2007. Two years later, Smith & Nephew told the FDA that the Deferred Prosecution Agreement was causing "significant time delays" in its efforts to implement the clinical study, due to additional contractual requirements

for hiring surgeons to monitor patients. In the same correspondence to the FDA, dated Sept. 14, 2009, Smith & Nephew stated that it had contacted "close to 80 surgeons" about the study but none had showed interest in participation because they thought the study was too long, and/or the surgeons were not implanting enough BHR devices to meet the study's enrollment goals.

206. A similar post-approval study of patients in the UK was also plagued by poor follow-up rates for patients and a lack of information. For example, on Nov. 13, 2006, just months after the PMA process was complete, the FDA wrote a letter to Jennifer Reavis, Clinical Affairs Specialist at Smith & Nephew, stating that the nine-year follow-up rate for UK patients was just 29.4 percent, far below the FDA's benchmark follow-up rate of at least 80 percent. The FDA wrote in the letter that the poor follow-up rate raised concerns about bias, and the agency demanded that Smith & Nephew take steps to increase follow-up rates. On information and belief, Smith & Nephew never took adequate steps to comply.

207. In addition to poor patient follow-up rates, Smith & Nephew prematurely closed the Study's U.S. patient database on March 19, 2012, before the planned completion date, and thus did not comply with the terms of the PMA. On several occasions, the FDA reported the status of the BHR Study was "progress inadequate" in part because patient enrollment milestones were not met, and because it failed to timely submit scheduled reports to the FDA pursuant to 21 CFR § 814.84, *et. seq.* Mandatory reports for the study were submitted late to the FDA at least three times in the last eleven years — in Nov. 2006, July 2011 and May 2017. Documents submitted by Smith & Nephew to the FDA in May 2013 show that of the eight planned "investigational" sites for the PMA study, only four were operational at the time, while a fifth had dropped out due to slow patient enrollment and three others were still "pending site initiation, contract execution and … approval."

208. Smith & Nephew's promises to the FDA about training surgeons are further evidence of its violations of the PMA's terms. Smith & Nephew agreed to implement a training program as part of the PMA including quarterly teleconferences with surgeons during the first two years of the U.S. portion of the safety study, and Smith & Nephew agreed to provide the FDA with an analysis of adverse events and complaints related to the BHR system.

209. Smith & Nephew began the BHR training program for surgeons on December 13, 2006, but it failed to achieve the training milestones it promised to the FDA, and the company in fact did not begin widespread training until late 2009 — more than three years after the BHR became available in the U.S. — when it admitted to the FDA that surgeons were performing resurfacing operations despite having not been trained at all by Smith & Nephew in how to properly perform the resurfacing procedure.

210. Underscoring the critical safety hazards associated with this lack of training, BHR designer and inventor Dr. Derek McMinn now claims that the high failure rate of the BHR is due in part to the steep "learning curve" for newer surgeons. McMinn, who boasted that he designed the BHR in his garden shed, in a June 2015 lecture claimed that this learning curve requires a surgeon to perform 1,000 surgeries with the BHR in order to master the operation. Smith & Nephew never informed surgeons, the FDA, or patients, including Plaintiffs, that they would be subject to a higher risk of revision surgery if their doctor had not performed at least 1,000 operations.

211. Smith & Nephew also failed to provide the same training opportunities that it promised to the initial group of "core" U.S. surgeons who received training in England. In later years, for example, it did not provide cadavers for surgeons to practice implantation of the BHR, even though surgeons repeatedly asked for cadavers. In many cases, Smith & Nephew did not

provide live in-person training as promised, and instead referred surgeons to videos or brochures, or did not provide any training at all.

212. Although Smith & Nephew failed to follow its own training protocol, which was a requirement of the PMA, Dr. McMinn did not hesitate to blame those same inadequately trained surgeons for the BHR's high failure rate. For example, in August 2011, four years before the BHR was finally recalled, Dr. McMinn published an article on his website titled "Metal Ions Questions & Answers" in which he attempted to distinguish the BHR from other problematic and failure-prone metal-on-metal hip devices, including the DePuy ASR. Dr. McMinn placed the blame for these failures on surgeons who improperly placed the device, and on patients themselves, particularly women, whom he claimed are "'pre-sensitized' to metal due to the usage of costume jewelry etc. and their tissues may "over-react" to low levels of nickel released from artificial devices." (*sic*). Dr. McMinn did not offer any scientific evidence for his theory about the connection between costume jewelry and failure rates for the BHR.

D. Smith & Nephew Never Completed Terms and Requirements of the PMA

213. Smith & Nephew's failure to comply with the PMA as described herein is evident through the following non-exhaustive list:

a. Smith & Nephew allowed and encouraged its commission-based salesmen to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the BHR system but delayed its reporting to the FDA;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise its instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the BHR;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons — both overseas and domestically — upon whose data it relied to boast a high success rate for the BHR had been paid financial remuneration in order to use and promote the BHR;

j. Smith & Nephew willfully ignored the existence of numerous complaints about failures associated with components of the BHR that were being used in illegal combinations throughout the United States when, in fact, those revision surgeries should have been thoroughly investigated because such usage constitutes an unlawful design change and would provide insight into possible problems that may

not be readily seen when the BHR system was used as a completed, unaltered system;

k. Smith & Nephew, as a result of increased demand for the product, failed to properly train all surgeons and Original Core Surgeons using the product as required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA, and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

l. Smith & Nephew also misrepresented to the surgeons in the United States that *in vivo* testing of the BHR had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable; and,

m. Smith & Nephew failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the BHR system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

n. Smith & Nephew failed to manufacture the BHR System with material that met the FDA's requirements for hardness, durability, composition, and finish, in violation of 21 C.F.R. § 814.80.

o. Smith & Nephew failed to warn surgeons and patients that the learning curve for implanting the BHR was so steep - as many as 1,000 surgeries - and that data presented to the medical community and patients from McMinn and Treacy was skewed because the surgeons were the inventing surgeons and therefore had more experience and familiarity with the product. This increased the risk to patients and Plaintiffs of increased wear, increased metal debris, and increased need for revision surgery.

214. This cause of action is based entirely on the contention that Smith & Nephew violated federal safety statutes and regulations, as well as the conditions established in the Approval Order with which Defendant agreed to comply. Plaintiff does not bring the underlying action as an implied federal statutory cause of action, but rather is pursuing parallel state law claims.

215. Smith & Nephew had an affirmative duty to update medical professionals as new risks associated with the BHR arose in the literature or S&N became aware of those new risks. While generally a device manufacturer has the discretion to supplement the PMA through the Changes Being Effected ("CBE") process, §814.39(d), the FDA on July 30, 2010, in an email from John Goode, advised Smith & Nephew that "it is necessary to update labeling for devices to ensure patients and physicians are appropriately educated." Specifically, the FDA ordered S&N to use the Special PMA Supplement procedure to strengthen certain warnings.

216. Beginning July 30, 2010, if not earlier, S&N was under an affirmative duty to use the CBE process to update its labeling without FDA approval or without waiting for the FDA to order it to do so as new risks arose and S&N learned of them. S&N failed to comply with this duty,

or only did so after being forced by the FDA to take actions that it should have undertaken voluntarily.

217. Further, Smith & Nephew used the CBE process to update its labeling about the safety of the BHR as it related to pseudotumors in December 2009, and the FDA approved S&N's proposed labeling change one day after it was submitted via email. Once S&N used the CBE process to strengthen its warning, it assumed a duty to continue to update its labeling as new information about the safety of the BHR developed through the same process.

218. Beginning in December 2009 and/or July 30, 2010, until the recall in September 2015, S&N learned of many new risks of the BHR, including huge increased risks of revision in women and patients using the smaller joint sizes, as well as the general failure of all metal-on-metal devices as discussed above. Throughout this time period, S&N's failure to update the labeling through the CBE process constitutes a violation of its duty under state law to properly warn that is parallel to its federally-imposed duty through the July 2010 FDA directive.

219. Had Smith & Nephew complied with this duty and updated its labeling, the medical community, patients and Plaintiffs would not have used the BHR and would not have been injured. S&N's failure to use the CBE process to update its labeling was the proximate case of Plaintiffs' injuries.

220. In sum, Smith & Nephew failed to comply with the specific directions of the FDA and with the specific conditions of the PMA. Had Smith & Nephew complied with the terms of the PMA and the FDA directives, Plaintiffs would not have had the BHR implanted and would not have been injured by the BHR. Additionally, failure to complete the terms of the PMA and follow the FDA directive increased the injuries of Plaintiffs who would have been monitored more closely and earlier than they were, and whose revision surgeries would have taken place earlier than they

did. Smith & Nephew's failure to do so caused years of additional pain and suffering and increased the toxic metal wear debris in Plaintiffs' bodies.

221. As discussed more fully below, Smith & Nephew undertook the duty to comply with the PMA under common law principles, and the PMA and FDA directives defined S&N's duty of reasonable care under state laws and statutes that operate independently from and parallel to the federal requirements.

V. The BHR Was Manufactured Defectively

222. An investigation and wear analysis of an explanted BHR device conducted by Smith & Nephew itself showed maximum linear wear of 5.9 μm for the femoral head, 6.1 μm for the acetabular cup, and combined linear wear for both components of 12.0 μm. The results of the investigation, described in a July 1, 2016, letter from Tina Mueller, Senior Regulatory Compliance Specialist for Smith & Nephew, to Ryan Gregoire of Smith & Nephew, show a linear wear rate for the BHR well in excess of the average annual linear wear rate of 1 μm for even earlier metal-on-metal hip devices from the 1960s as determined by Schmalzried, et. al., *Long-duration Metal-on-Metal Total Hip Arthroplasties with Low Wear of the Articulating Surfaces*, J. Arthroplasty. 1996 Apr; 11(3):322-31. This rate also exceeds the linear wear rate identified by Smith & Nephew in its own tribological studies using a wear simulator machine. The BHR system therefore is defective because it fails to meet manufacturing specifications for hardness, durability, composition, and finish, in violation of 21 C.F.R. § 814.80.

223. Plaintiffs have requested, but have not yet received, a series of exemplar BHR devices from Smith & Nephew for the purposes of independent wear and hardness testing. However, numerous other tests of explanted devices conducted by Smith & Nephew itself show wear rates far beyond the expected level of wear for the devices. For example,

224. The clearance tolerances for the BHR device also were not met, and/or were responsible for generating large amounts of metal debris, particularly in female patients and those with small joint sizes. For example, in numerous tests performed on the explanted failed devices of 19 patients in Smith & Nephew's post-approval clinical study, analysis showed far higher wear rates than expected. Although Smith & Nephew could have performed additional testing on these and other devices, and discovery is not yet available to fully demonstrate the extent of this testing, these tests further confirm the manufacturing defects in the BHR. For example, testing on the explanted BHR device for Patient 1526 in the clinical study showed maximum linear wear of 35.1 μm for the femoral head and 31.4 μm for the BHR cup. Smith & Nephew failed to further investigate the reasons for this excessive wear rate. Similarly, testing on the device for Patient 1045 in the study showed maximum linear of 76.3 μm for the head, well above the expected wear rate. But even though these and other patients were part of Smith & Nephew's own clinical study, the company claimed that it couldn't conduct further investigation on these manufacturing defects because it didn't have supporting medical records and other documentation.

225. Evidence of improper clearances for the BHR femoral head and cup, and Smith & Nephew's awareness of these problems, are further illustrated in a September 2008 report written by Dr. Koen de Smet called Birmingham Hip Resurfacing Versus Conserve Plus Metal-on-Metal Resurfacing, A Surgeon's Perspective (http://www.surfacehippy.info/pdf/bhvsrconserv.pdf). This report was published alongside paid advertising from Smith & Nephew promoting the BHR. Smith & Nephew previously stated that the radial clearance, or free space, between the articulating femoral head and acetabular cup of the BHR, was approximately 100 microns. However, in his report, barely two years after the PMA was granted, Dr. de Smet found an average clearance of 271 microns, and noted that "[o]ne of the worst cases of metallosis I saw in my revision series was

a BHR with clearance of 400 microns and total wear depth of nearly 200 microns! The higher clearance in the BHR could be one of the factors why this resurfacing is having higher blood metal ion levels than other resurfacings [Back et al, 2005] [Witzleb et al, 2007]. There is no good explanation so far why we would need such a high clearance."

226. Smith & Nephew was aware of these inconsistencies and defects in their manufacturing process. In 2009, Defendant received a report of patient "PD," whose femoral head linear wear was found to be 8.5 μm, in excess of the maximum linear wear rate, with Defendant noting that "the position of wear on the femoral head is outside the expected region." Additionally, various "fine" and "rough" scratch marks were also found on patient PD's device. Smith & Nephew, rather than investigating its own manufacturing process, indicated that patient PD's usage of the device was the cause of femoral head's excessive wear rate and "fine" scratches, and the revision surgery was the cause of the "rough" scratches on the device.

227. Smith & Nephew also noted, in relation to patient PD's device, that "repeat dislocations can result in higher than expected wear to the repeated movement of the head outside the intended bearing surfaces . . . it has been determined that the slightly elevated wear noted in [PD's] retrieval report is very unlikely related to any manufacturing related process, but rather a factor of the patient's implanted condition and dislocations." Thus, rather than investigating its own manufacturing process, Defendant simply passed blame for the above manufacturing issues onto the patient, who received the device in the same condition of when it left the Defendant's control.

228. Independent studies of the BHR device also showed radial clearance in excess of Smith & Nephew's own standards. For example, a study of 10 resurfacing devices published in 2009 showed radial clearance for the BHR was greater than the 100 micron standard in Smith &

Nephew's design files, greater than all but two of the other devices in the study, and far greater than the mean clearance of 84.86 for all 10 devices. Heisel, et. al., *Ten Different Hip Resurfacing Systems: Biomechanical Analysis of Design and Material Properties*, Int. Orthop., 2009 Aug; 33(4): 939-943, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2898991/.

229. Lower radial clearance generally results in smaller amounts of wear on the devices. The excessive radial clearance for explanted BHR devices is further evidence of a manufacturing defect, which is not due to surgical technique or patient activity. On information and belief, and subject to additional discovery from Smith & Nephew, similar disparities exist between Smith & Nephew's design file and the measurements of explanted devices for wall thickness, surface roughness, hardness, and sphericity of the components. These deviations are further evidence of a manufacturing defect, which results in excessive wear, edge loading, breakaway wear and other phenomena leading to failure.

SMITH & NEPHEW IS SUBJECT TO COMMON LAW DUTIES UNDER NUMEROUS LONG-STANDING STATE LAW PRINCIPLES

I. Smith & Nephew Voluntarily Assumed Various State Law Duties

230. Under longstanding common law in each state where Plaintiffs reside, a defendant can voluntarily assume or affirmatively undertake a duty of care through their representations, statements, words, and actions.

231. By agreeing to only sell the BHR under the conditions listed in the PMA, by making affirmative representations about surgeon skill on its website, by communicating to the medical community and Plaintiffs outside the label about the safety of the device, and by and through its other affirmative actions as described above, Smith & Nephew assumed a duty of reasonable care to carry out its obligations of the PMA and to update the medical community and Plaintiffs about the safety of its device.

232. A manufacturer can affirmatively undertake a duty to properly train, instruct, or assist a physician on the surgical implantation of its device, and Smith & Nephew did so here.

233. First, Smith & Nephew assumed the FDCA duty to be truthful to the FDA and to others about the safety of the BHR through voluntary conduct under state law. In an attempt to increase sales and convince the surgeons, medical community, patients, public, and FDA that its metal-on-metal BHR devices were safe, Smith & Nephew voluntarily undertook a duty to provide truthful, current information about the safety of the BHR devices each time it made its false and misleading representations.

234. Smith & Nephew then failed to exercise reasonable care to perform its undertaking to provide the surgeons, medical community, patients, public, and FDA with current, truthful information about the safety of the BHR.

235. Smith & Nephew should have recognized, and in fact did recognize, at the time those representations were made, that providing truthful, current information about the safety of the BHR was necessary to protect patients from increased risks of harm, including serious injury.

236. Smith & Nephew should have recognized, and in fact did recognize, at the time those representations were made, that providing truthful, current information about the safety of the BHR devices would cause the surgeons, medical community, patients, public, and FDA to rely on those representations for the BHR use—which they did.

237. Moreover, once Smith & Nephew made those false and misleading representations, an additional duty to correct and clarify the misrepresentations with current and accurate information concerning the safety of the BHR was imposed on Smith & Nephew because, without correcting and clarifying its misrepresentations, Smith & Nephew would and did create an unreasonable risk of serious harm to patients, including Plaintiffs.

238. Smith & Nephew's failure to exercise reasonable care to perform its undertaking to provide the surgeons, medical community, patients, public, and FDA with current, truthful information about the safety of the BHR, and its subsequent failure to correct and clarify those misrepresentations, foreseeably caused Plaintiffs the physical harm of which they complain in this amended complaint.

239. Smith & Nephew assumed various state law duties by voluntarily agreeing—and in fact, demanding—to train physicians to implant the BHR resurfacing product using its exact methods. As noted above, as part of the PMA, Smith & Nephew began a BHR training program for surgeons on December 13, 2006, including quarterly teleconferences during the first two years of the U.S. portion of the safety study.

240. But that training program failed to achieve the milestones Defendant promised to the FDA. Moreover, Smith & Nephew did not begin widespread training until late-2009—more than three years after the BHR became available in the U.S.—when it admitted to the FDA that surgeons were performing resurfacing operations despite Smith & Nephew not training them in how to properly perform the procedure.

241. Defendant's own direct to consumer website, rediscoveryourgo.com/bhrbirminghamhipresurfacing.aspx, which advertised the supposed advantages and benefits of the BHR, advocated the necessity of proper training: "Not every orthopedic surgeon is trained to use **BIRMINGHAM HIP Resurfacing**. Find the surgeons in your area who use BIRMINGHAM HIP Resurfacing by entering your ZIP code or city and state below." The website provides a search engine that allows potential patients to find a "trained" surgeon to install the BHR resurfacing product.

242. Further, even the primary webpage for the BHR (www.smith-nephew.com/professional/products/all-products/bhr-birmingham-hip-resurfacing/) device provides that "[t]he BHR is intended for use only by surgeons who have received appropriate training and are familiar with the implant components, instruments, surgical technique (including with the importance of correct positioning), clinical applications, adverse events and associated risks."

243. As required by 21 C.F.R. § 803.3, Smith & Nephew also agreed to voluntarily provide to the FDA an analysis of adverse events and complaints related to the BHR system. But Defendant failed to satisfy that requirement.

244. By agreeing to only sell the BHR under the conditions listed in the PMA, by making affirmative representations about surgeon skill on its website, and through its other affirmative actions as described above, Smith & Nephew assumed a duty of reasonable care to carry out its obligations of the PMA.

245. As discussed above and incorporated herein, Smith & Nephew made numerous misrepresentations to the medical community, the general public, and potential patients, touting the safety of Smith & Nephew's BHR device.

246. By providing information to the medical community and directly to patients about the safety of the BHR from third parties like the British health authorities or independent studies, outside of the FDA-approved labeling, Smith & Nephew voluntarily assumed a duty to use reasonable care to update the medical community and patients, including Plaintiffs, about new information about the safety of the BHR. Smith & Nephew violated its duties by not updating the medical community and patients, including Plaintiffs, about new information about the safety of

the BHR from the same sources Smith & Nephew had previously cited as proof of the BHR's safety. These violations caused Plaintiffs' injuries.

247. Smith & Nephew violated its voluntarily assumed duties by not appropriately training surgeons or sending adverse event reports to the FDA

248. According to federal duties imposed by the PMA, Smith & Nephew had the on-going duty to provide the FDA with adverse event and defective device reports regarding the BHR. In a majority of states, there is a parallel state duty to monitor the sale and use of the BHR, to discover defects associated with the BHR, and to warn the medical community, consumers, and Plaintiff of any dangers associated with the device.

II. The BHR Was Misbranded Under FDCA And Parallel State Statutes

249. A device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended, or suggested in the labeling thereof. 21 U.S.C. § 352(a) & (j).

250. The "labeling" of a device pursuant to the FDCA and FDA regulations includes not only labeling specifically approved by the FDA but also includes all written, published or other material which the manufacturer publishes or distributes relating to the device in addition to materials specifically approved by the FDA. Such material may include advertising or promotional material distributed in relation with the device.

251. A "misbranded" device is prohibited for introduction into interstate commerce by the FDCA. 21 U.S.C. § 331(a).

252. The BHR System provided a "Patient Information" document to patients receiving BHR implants. These documents constitute "labeling" under 21 U.S.C. § 321(m).

253. The "Patient Information" document failed to reference the risk of metallosis in its "Potential Risks" section for years, even though S&N knew or should have known of the risk of metallosis based on the studies it submitted or referenced as part of its PMA application and documents it provided to implanting physicians.

254. Although Smith & Nephew was in the best position to make changes to its device labeling, it only updated the Patient Information section after being told to do so by the FDA. For example, in 2009, at the FDA's request, Smith & Nephew added a new warning about pseudotumors forming in patients due to high levels of wear debris. By omitting any further mention of metal ion release, metallosis, or similar problems, this statement and the document misleadingly suggest that metal ions from the BHR System do not otherwise pose a risk to patients and Plaintiffs. Smith & Nephew made this misleading omission even though the company knew about the risks of metallosis and even used the term metallosis years earlier. For example, the Summary of Safety and Effectiveness Data for the BHR, dated May 11, 2005, mentions "metallosis" along with "metal sensitivity reactions" as a potential adverse effect for patients.

255. Similarly, Smith & Nephew failed to include a warning about the high risk of revision for female patients and those with smaller joint sizes, even though it knew about this risk for years. Just as it mislead the public with marketing materials, online promotions, and direct-to-consumer advertising that downplayed the risks of metallosis, Smith & Nephew buried the harmful evidence about the BHR's failure rate for women and smaller-sized men.

256. S&N knew or should have known (1) that because of the learning curve for the BHR, survivorship rates in its studies were misleading and could not be replicated in the real world; (2) that failure rates were higher than were reported by S&N; (3) that adverse reactions to metal debris causing the need for revision can take longer than 5 years, making the data about 5-year

survivorship incomplete and misleading; (4) that the McMinn study lost track of some patients, thus skewing the failure-rate downward; and (5) that real-world failure rates were higher than the clinical studies to which the "Patient Information" document refers. As a result, the "Patient Information" document's representations regarding revision rates and effectiveness rates misleadingly suggested the BHR system was more effective and less likely to require revision than it actually was.

257. S&N therefore had information that it knew or should have known made information in the labeling false or misleading.

258. Because such information in the labeling was false or misleading, the device was misbranded under 21 U.S.C. §§ 321(n) and 352(a).

259. Under 21 U.S.C. § 352(t), the device was also misbranded per se because Smith & Nephew failed to furnish material and information required by 21 U.S.C. § 360i.

260. Under 21 U.S.C. § 352(t), the device was also misbranded per se because Smith & Nephew was ordered at the time of the device's approval to conduct a post-market approval study under 21 U.S.C. § 360*l*, which order Smith & Nephew failed to comply with.

261. Smith & Nephew had information that it knew or should have known made information in the label false or misleading.

262. Because such information in the label was false or misleading, the device was misbranded under 21 U.S.C. § 352(a) and 21 U.S.C. § 331(q)(2).

263. Under 21 U.S.C. § 352(t), the device was misbranded per se because Smith & Nephew failed to furnish material and information required by 21 U.S.C. § 360i.

264. Under 21 U.S.C. § 352(t), the device was misbranded per se because Smith & Nephew was ordered at the time of the device's approval to conduct a post market approval study under 21 U.S.C. § 360l, with which Smith & Nephew failed to comply.

III. Smith & Nephew Fraudulently Concealed Plaintiffs' Claims

265. Smith & Nephew fraudulently concealed the fact that it did not actually have the legal protection provided of preemption under the PMA. Smith & Nephew failed to disclose information to the scientific and medical communities, as well as consumers, in violation of its duty to disclose. The information purposely withheld was material, and was information that consumers, such as Plaintiff could not have learned without Smith & Nephew's disclosure.

266. Specifically, Smith & Nephew intentionally withheld from consumers the fact that it no longer enjoyed PMA protection; at a minimum, this material fact was intentionally withheld from the public, and consumers such as Plaintiff, until the formal recall in September 2015, and even thereafter, as Smith & Nephew continued to assert that it enjoyed preemption protection from all claims. Accordingly, consumers, such as Plaintiff, were misled into believing that they had no claim for the injuries suffered due to the BHR system.

267. Because Smith & Nephew intentionally withheld this material information concerning the PMA status, numerous Plaintiffs were harmed by relying on the nondisclosure, and acted on such reliance.

268. Because Smith & Nephew continues to maintain that it has PMA protection from all claims, and because of the fraudulent concealment of material facts, Plaintiff is well-within the statute of limitations at the time of this filing. Plaintiffs' statute of limitation would have begun to run from the recall date in September 2015, or the date of his revision surgery, whichever is later.

269. Defendant fraudulently concealed from and/or failed to disclose to Plaintiffs, Plaintiffs' healthcare providers, and the medical community that its BHR resurfacing products were defective, unsafe, and unfit for the purposes intended, and that they were not of merchantable quality.

270. The facts concealed and/or not disclosed to Plaintiff and the medical community were material facts that a reasonable person would have considered important in deciding whether to utilize Defendant's BHR resurfacing products.

271. Defendant's fraudulent concealment, as complained of herein, constitutes a parallel violation of common law of all states where Plaintiffs reside that predates and operates independently from the above federal requirements.

IV. Smith & Nephew's State Law Duties Are Defined by Federal Regulations, The PMA, And Other FDA Actions

272. Smith & Nephew is subject to a duty of reasonable care under the common law in each state in which Plaintiffs reside, and this common law duty can be set, defined by or otherwise informed by federal statutes, regulations and other FDA actions. To the extent these duties are parallel with Smith & Nephew's requirements under federal law, Plaintiffs' claims arising from violations of these duties are not preempted by federal law.

273. Specifically, Smith & Nephew's conduct violated the FDCA and gave rise to recovery under state law, even in the absence of the FDCA, because, as relevant to this section, Plaintiffs' state law duties are defined by the FDCA and its attendant regulations and approval order; and because Smith & Nephew made voluntary statements outside the label about the safety of the BHR.

274. As detailed above, Smith & Nephew made statements and representations outside the FDA-approved labeling to surgeons and the medical community about the safety of the BHR

that were false and materially misleading, including that the BHR: was safer than it was, safer than other metal-on-metal devices, safer than ceramic hip devices, had lower failure rates; and Smith & Nephew omitted material facts from sources that were later updated to cast doubt on the safety of the BHR.

275. Smith & Nephew was also required by the FDCA and its corresponding regulations and approval order, detailed supra Section IV, to comply with post-approval obligations, such as: updating the FDA with current failure rates, complying with specific reporting, investigative, and performance-related duties; and properly training surgeons using the BHR devices.

276. Smith & Nephew's FDCA-imposed duties arose out state law contract principles. Smith & Nephew's duty to provide current, truthful information to the FDA and others about the safety of the BHR arose out of the performance of a contract where Smith & Nephew expressly and impliedly agreed that it would provide the safety-related information to the FDA and others in a truthful, current manner (and satisfy the attendant FDCA requirements), during the PMA approval process, and through timely supplementation following the approval process (as stated in the Approval Order)—in exchange for the right to sell the BHR within the United States.

277. Smith & Nephew received and accepted the benefit without materially satisfying its bargained-for performance obligations.

278. Smith & Nephew's duty to provide current, truthful information to the medical community and public about the BHR also arose out of contract principles where Smith & Nephew expressly and impliedly agreed with the FDA that any voluntary representations made to the public (or others outside the FDA) about the BHR would be truthful and otherwise in compliance with the Approval Order—in exchange for the right to sell the BHR within the United States.

279. Smith & Nephew received and accepted the benefit without materially satisfying its bargained-for performance obligations.

280. Smith & Nephew's FDCA-imposed duties to be truthful about the safety of the BHR arose out of its special relationship with the surgeons, medical community, patients, public, and FDA. Smith & Nephew performed important services to medical professionals and, indirectly to patients, by manufacturing, marketing, and selling the BHR products that would be implanted in patients' bodies, and if performed improperly and based on false and misleading information, would have catastrophic consequences.

281. Smith & Nephew had a duty to disclose this information to the medical professionals who would then select and implement the best medical treatment plan for Plaintiffs' hip-related conditions.

282. Smith & Nephew was in a unique position of trust and confidence by not only manufacturing, marketing, and selling the BHR, but also by funding and conducting its own studies on which it relied to demonstrate the safety of BHR, and then failing to disclose its relationship to those studies—and citing specific literature and research later shown to be false and misleading.

283. Smith & Nephew's relationship with them was of a nature where it would be expected that the FDA, medical providers, and patients in need of hip replacement would rely on the representations Smith & Nephew made about the safety of the BHR, and later lack of clarification would reasonably be taken as an appearance of safety.

284. The surgeons, medical professionals, patients, and FDA detrimentally and justifiably relied on Smith & Nephew's safety-related representations, which caused Plaintiffs their serious injuries, as described in this amended complaint.

285. Smith & Nephew had a duty to correct these misrepresentations and dangers caused by BHR, because it should have known, and in fact did know, the information served a serious purpose; the surgeons, medical community, patients, public, and FDA intended to rely and act on it; the information was materially false or misleading; and the information would cause Plaintiffs serious injury.

286. Smith & Nephew's FDCA-imposed duties were adopted as the standard of care under Plaintiffs' state laws—a violation of which constitutes negligence *per se*. The FDCA, with its attendant federal regulations and approval order, impose specifically defined duties on Smith & Nephew with which it must comply to sell the BHR devices in the United States, detailed supra Section IV, including: to ensure the safe and effective use of the device through specific reporting, investigative, and performance-related requirements.

287. These duties are imposed on Smith & Nephew for the purpose of protecting patients, like Plaintiffs, from the very kind of injuries of which they complain in this amended complaint.

288. By failing to comply with the federally-imposed duties through untruthful, misleading, and materially incomplete disclosures and information to the FDA during and after PMA approval, and to the surgeons, medical community and public by voluntary disclosure about the safety of the BHR, Smith & Nephew has proximately caused Plaintiffs' injuries.

289. Smith & Nephew had actual or constructive knowledge that Plaintiffs and other patients in Plaintiffs' position would rely upon said misrepresentations and/or suppressions when making decisions about surgery that involved the BHR, and Plaintiffs and other patients did in fact rely upon these misrepresentations and/or suppressions as described above.

290. Each of these FDCA violations constitute a *per se* violation of negligence under Plaintiffs' state law claims.

291. The FDA specifically told Smith & Nephew on July 30, 2010, that "As new risks arise, it is necessary to update labeling for devices to ensure patients and physicians are appropriately educated." The FDA told Smith & Nephew to use the Special PMA Supplement label change process to update its label. While this process is generally a discretionary process, the FDA communicated to Smith & Nephew that this process was "necessary" when "new risks arise."

292. Thus, Smith & Nephew could change its labeling without FDA approval, and had an affirmative duty to use the Special PMA Supplement label change process to change its labeling when information about new safety risks arose.

293. Smith & Nephew violated its duty to update its labeling through the Special PMA Supplement process after July 30, 2010, and that violation caused Plaintiffs injuries.

V. Smith & Nephew Had A Continuing, Post-Sale Duty to Warn the Medical Community of Dangers Associated With the BHR

294. According to duties imposed by the PMA, Smith & Nephew had the on-going duty to provide the FDA with adverse event and defective device reports regarding the BHR. In the majority of states where Plaintiffs reside, there is a parallel state duty to monitor the sale and use of the BHR, to discover defects associated with the BHR, and to warn the medical community, consumers, and Plaintiff of any dangers associated with the device after the original implantation of the device. As discussed above and incorporated herein, Smith & Nephew made numerous representations to the medical community, the general public, and potential patients, touting the safety of Smith & Nephew's BHR device over the course of several years.

295. Smith & Nephew left the impression with surgeons and the medical community that the failure rate of the BHR was lower than it really was - and that the BHR was safe - by failing to provide updated studies and survivorship, including Smith & Nephew's own PMA-mandated studies.

296. Specifically, Smith & Nephew had actual and constructive knowledge of the risks associated with the BHR device, and failed to post-sale warn the medical community, consumers, and Plaintiff in particular:

a. Smith & Nephew was obligated and failed to take reasonable efforts to issue a post-sale warning to the medical community, consumers, and the Plaintiff of the defective and unreasonably dangerous condition associated with the BHR device that was available either at the time of distribution or in sufficient time before Plaintiffs' injury so that an effective and reasonable supplemental warning could have been given; and/or

b. Smith & Nephew was obligated and failed to take reasonable efforts to warn the medical community, consumers, and Plaintiff of the defective and unreasonably dangerous condition associated with the BHR device that was unknown at the time of sale but which was subsequently discovered after the sale of the device; and/or

c. Smith & Nephew failed to take reasonable efforts to issue a post-sale warning after learning of the BHR's high failure rates and risks associated with metal ions when a reasonable person in Smith & Nephew's position would have provided such a warning to the medical community, consumers, and the Plaintiff in particular; and/or

d. Smith & Nephew had the obligation to and failed to take reasonable efforts to issue a post-sale warning when it knew or should have known of significant hazards associated with misuse or alteration of the BHR device. The foreseeable use of the BHR device was unreasonably unsafe and Smith & Nephew was required to warn the medical community, consumers, and the Plaintiff; and/or

e. Smith & Nephew had the obligation and failed to take reasonable efforts to issue a post-sale warning after the initial sale of the BHR device because it commenced and/or had knowledge of safety-related research sufficient to induce the medical community, consumers, and the Plaintiff to reasonably expect Smith & Nephew to disseminate hazard information.

297. Smith & Nephew's failure to carry out its duty to post-sale warn caused Plaintiffs' injuries.

298. Smith & Nephew's failure to carry out its duty to post-sale warn was a proximate cause of Plaintiffs' injuries; and/or

299. Smith & Nephew's failure to carry out its duty to post-sale warn was a direct cause of Plaintiffs' injuries; and/or

300. Smith & Nephew's failure to carry out its duty to post-sale warn was a substantial factor resulting in Plaintiffs' injuries.

CAUSES OF ACTION

COUNT I
STRICT PRODUCTS LIABILITY

301. Plaintiffs incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

302. Defendant designed and/or manufactured the BHR Systems implanted in Plaintiffs' bodies, in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to it, as well as the duties created by virtue of the agreements in the Approval Order.

303. At the time the BHR Systems, including the Acetabular Cups and Femoral Heads, left the control of Defendant, Smith & Nephew, they were unreasonably dangerous due to Defendant's non-compliance with the Act, and the regulations promulgated pursuant to it and the Approval Order in one or more of the following ways:

a. Failed to accurately establish the in vivo life expectancy of the BHR, in violation of 21 C.F.R. § 820.30(f);

b. Failed to validate the anticipated wear of the acetabular cup prior to its release into commercial distribution, in violation of 21 C.F.R. § 820.30(g). For example, as recently as 2012, Smith & Nephew admitted to the FDA that *in vitro* wear data from machine simulators had little clinical relevance to the performance of the BHR implant *in vivo*;

c. Failed to establish and maintain appropriate reliability assurance testing to validate the BHR design both before and after its entry into the marketplace, in violation of 21 C.F.R. § 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the BHR's latent propensity to effuse metallic contaminants into the human blood and tissue. Instead of conducting adequate studies, Smith & Nephew attempted to blame bio-compatibility studies on, among other things, patients who wear costume jewelry;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. § 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. § 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the BHR, returned BHR, and other quality problems associated with the BHR, in violation of 21 C.F.R. § 820.100;

h. Failed to appropriately respond to adverse incident reports and complaints that strongly indicated the acetabular component was Malfunctioning [as defined in 21 C.F.R. § 803.3], or otherwise not responding to its Design Objective Intent, in violation of 21 C.F.R. § 820.198. For example, instead of adequately investigating these incidents, Smith & Nephew in its PMA annual reports to the FDA blamed catastrophic product failures of the BHR on generalized issues such as "pain" or "squeaking" or "allergic reaction";

i. Failed to conduct complete device investigations on returned BHR and components, including the acetabular component, in violation of 21 C.F.R. § 820.198;

j. Continued to place the BHR into the stream of interstate commerce when it knew, or should have known, that the acetabular component was Malfunctioning [as

defined in 21 C.F.R. § 803.3] or otherwise not responding to its Design Objective Intent; and/or,

k. Failed to investigate reports of User Error so as to determine why User Error was occurring and to try to eliminate User Error in the future through improved physician training.

304. Smith & Nephew's failure to comply with the above-stated requirements is evident through the following non-exhaustive list of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant:

a. Smith & Nephew allowed and encouraged its commission-based salesmen to not report adverse events and complaints such as revision surgeries, thereby substantially reducing the known and reported incidence of product problems;

b. Smith & Nephew willfully ignored the existence of numerous adverse events and complaints, such as revision surgeries, which it knew or should have known were not being reported to the company or the FDA;

c. Smith & Nephew received hundreds of adverse reports regarding the BHR system but delayed its reporting to the FDA;

d. Smith & Nephew failed to properly communicate adverse events to the FDA, when it did report them, and when doing so, wrongly attempted to blame others for the adverse events;

e. Smith & Nephew also failed to analyze the adverse events and revision surgeries of which it was aware to determine why so many revisions were required so soon after implantation;

f. Smith & Nephew failed to investigate and report on "unanticipated events," i.e., any adverse event not listed on the label;

g. Smith & Nephew failed to investigate all Device Failures;

h. Smith & Nephew failed to revise its instructions to doctors and its surgical techniques documents to reflect the true problematic experience with the BHR;

i. Smith & Nephew also knew but failed to disclose that some of the surgeons — both overseas and domestically — upon whose data it relied to boast a high success rate for the BHR had been paid financial remuneration in order to use and promote the BHR;

j. Smith & Nephew, as a result of increased demand for the product, failed to properly train all surgeons and Original Core Surgeons using the product as required by the Approval Order by using shortcuts, such as teaching surgeons by satellite instead of hands on as it had assured the FDA and by failing to require those surgeons to receive such training directly from the product designers in the United Kingdom or from Original Core Surgeons;

k. Smith & Nephew also misrepresented to the surgeons in the United States that *in vivo* testing of the BHR had been undertaken when Defendant, in fact, knew or should have known that the testing was invalid and the results unreliable;

l. Smith & Nephew represented to medical professionals and Plaintiffs that the BHR was safer than other metal-on-metal devices, had a low revision/failure rate, and was safe for use by communicating statistics and actions from health authorities, but failing to update the medical community and Plaintiffs when additional information became available and as new risks arose, leaving a false impression in

the minds of the medical community and plaintiffs about the safety of the BHR; and

m. Smith & Nephew failed to timely supplement its labeling as required in the Approval Order with information pertaining to the various failures of the BHR system, thereby misrepresenting the efficacy and safety of the BHR resurfacing products to the FDA and actively misleading the FDA, the medical community, patients, and public at large into believing that the BHR system was safe and effective when it was not by, among other things, claiming to have solved the problem of metal-on-metal friction due to a "fluid film" theory that has proven untrue.

305. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, a BHR System, including the acetabular cup and femoral head, was implanted in Plaintiffs' body, and failed and such failure directly and proximately caused and/or contributed to the severe and permanent injuries the Plaintiff sustained and endured as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiff, endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

306. This cause of action is based entirely on the contention that Smith & Nephew's actions that violated the state statutes and common laws listed below also violated parallel federal

safety statutes and regulations, as well as the conditions established in the PMA Approval Order with which Defendant agreed to comply to obtain premarket approval of the device.

307. Under Alabama law, the Alabama Extended Manufacturer's Liability Doctrine (AEMLD), Al. Civ. Pr. § 6-5-501, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

308. Under Alaska law, the BHR resurfacing products reached Plaintiffs without substantial change in the condition in which it was sold, and was used without inspection for defects and created a dangerous scenario for Plaintiffs and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

309. Under Arizona law, the risks of the BHR outweighed the potential benefit, and the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above.

310. Under Arkansas law, the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above.

311. Under California law, the BHR products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of

the potential safety hazards and failure modes, as alleged herein, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described here and above.

312. Under Colorado law, the BHR Resurfacing product, designed, manufactured, and sold by Defendant, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

313. Under Connecticut law, the BHR Resurfacing product, designed, manufactured, and sold by Defendant, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

314. Under District of Columbia law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

315. Under Florida law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it

left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

316. Under Georgia law, the BHR Resurfacing product, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

317. Under Hawaii law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

318. Under Idaho law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

319. Under Illinois law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the BHR product outweighed the benefits, beyond the expectations of an ordinary consumer, such as

Plaintiffs, and the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

320. Under the Indiana Product Liability Law**.,** Ind. Code § 34-20-4-1, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

321. Under Iowa law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the BHR product outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

322. Under Kansas law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the BHR product outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and

Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

323. Under the Kentucky Product Liability Act: Ky. Rev. Stat. Ann. § 411.300, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

324. Under the Louisiana Products Liability Act (LPLA), La. Rev. Stat. Ann. §9:2800.51-.53(7), the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

325. Under Maine law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein. The risks inherent in the BHR product outweighed the benefits, beyond the expectations of an ordinary consumer, such as Plaintiffs, and the BHR products reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

326. Under Maryland law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous

when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

327. Under Massachusetts law, the BHR Resurfacing product, when sold by Defendant, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

328. Under Michigan law, the BHR Resurfacing product, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the BHR product. Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

329. Under Minnesota law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

330. Under the Mississippi Product Liability Act (MPLA), Miss. Code Ann. § 11-1-63(a)(iii), the BHR reached Plaintiffs without substantial change in the condition in which it was

sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

331. Under Missouri law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

332. Under Mont. Code Ann. § 27-1-719, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

333. Under Nebraska law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

334. Under Nevada law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs

without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

335. Under New Hampshire law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

336. Under the NJPLA, N.J. Stat. Ann. § 2A:58C-1 through 58C-11, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

337. Under New York law, the BHR Resurfacing product, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the BHR product. Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as

described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

338. Under New Mexico law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

339. Under North Carolina Gen. St. § 99B-1-B-12, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

340. Under North Dakota law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

341. Under the Ohio Product Liability Act, Ohio Rev. Code Ann. §§ 2307.73(A) – 2307.77, the BHR reached Plaintiffs without substantial change in the condition in which it was

sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

342. Under Oklahoma law, the BHR Resurfacing product, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the BHR product. The risks of the BHR product because of these defects outweighed its benefits. Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

343. Under Or. Rev. Stat. §§ 30.920(1)(a) – (1)(b), the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

344. Under Pennsylvania law, the BHR Resurfacing product, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the BHR product. The risks of the BHR product because of these defects outweighed its benefits. Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein

and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

345. Under Rhode Island law, the BHR Resurfacing product, when sold, was not merchantable and reasonably suited to its intended use, and reached Plaintiffs without substantial change in the condition in which it was sold, and was unreasonably dangerous when it left the Defendant's possession. Moreover, at the time of distribution, a safer alternative design was available, was practicable, and would have reduced the risk of injury posed by the BHR product. The risks of the BHR product because of these defects outweighed its benefits. Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above. The likelihood of the injuries here was foreseeable by Defendant at the time the product left the Defendant's control.

346. Under the South Carolina Defective Products Act, S.C. Code Ann. § 15-73-10, the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

347. Under South Dakota law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

348. Under Tenn. Code Ann. § 29-28-102(2), the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

349. Under Tex. Civ. Prac. & Rem. Code Ann. § 82.005(a) – (a)(2), the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

350. Under Utah law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

351. Under Vermont law, the BHR Resurfacing products designed, manufactured and sold by Defendant were defectively designed and failed to include sufficient instructions and warnings of the potential safety hazards and failure modes, as alleged herein, and reached Plaintiffs without substantial change in the condition in which it was sold, were used without inspection for defect, and was unreasonably dangerous when it left the Defendant's possession. Plaintiffs' use of the device was entirely reasonable and foreseeable, and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described herein and above.

352. In Virginia, the BHR was unreasonably dangerous either for the use to which it would ordinarily be put and/or for some other reasonably foreseeable purpose, and the unreasonably dangerous condition existed when the goods left the defendant's hands.

353. Under the Washington Product Liability Act (WPLA), Wash. Rev. Code §§7.72.030(1), .030(2), .040(1), the BHR reached Plaintiffs without substantial change in the condition in which it was sold and Plaintiffs suffered injury and damages to themselves because of the BHR's defective condition, as described above, which made the product unreasonably dangerous.

354. Under the above states' laws, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

355. Thus, the above states' laws, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the varying state Legislatures to act in order to create such a remedy.

356. Under the above states' law, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of strict liability in tort.

357. Thus, under above states' law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the Legislatures to act in order to create such remedies.

358. The Act contains an express preemption provision, 21 U.S.C. § 360(k), which in relevant part states: "no state or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in

addition to, any requirement applicable under this Act [21 USCS §§ 301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301, et seq.]."

359. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 360(k) because the violations alleged are all based on an exclusively on state law claims that parallel federal statutory and regulatory set of requirements and express agreements with the FDA which include no "requirement which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. *See Bausch v. Stryker,* 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the extent they were based on the defendants' violations of federal law).

360. A defect out of compliance with the FDA's approved design are parallel to the state law duty to ensure that an unreasonable dangerous product is not sold in a defective condition.

361. As such, the claims set forth herein based on the facts alleged above contain requirements that are parallel to the Act and regulations promulgated thereunder.

COUNT II
NEGLIGENCE

362. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

363. As the designer, manufacturer, distributor and seller of the BHR, Smith & Nephew owed duties to the Plaintiffs of reasonable care under the circumstances. Those duties are defined by federal and state regulations, statutes, custom, practice, the terms of the PMA, and Smith & Nephew's voluntary actions and assumptions of duties, among other sources.

364. Smith & Nephew breached those duties of reasonable care to Plaintiffs by the actions detailed above, including, but not limited to, failing to warn Plaintiffs and the medical community of the true risks of the BHR, misrepresenting the true safety of the BHR, failing to comply with the terms of the PMA, failing to update the medical community and patients when it learned or discovered new information about the risks and safety of the BHR, and otherwise failing to recall the BHR before it did.

365. Smith & Nephew's breach of its duties caused Plaintiffs' injuries.

366. The BHR Systems, including the acetabular cups and femoral heads, implanted in Plaintiffs' hip were distributed and/or manufactured in violation of the Act and regulations promulgated to it.

367. Smith & Nephew consistently under-reported and withheld information about the likelihood of the BHR to fail and cause injury and complications, and has misrepresented the efficacy and safety of the BHR resurfacing products, actively misleading the medical community, patients, the public at large, and Plaintiffs.

368. Defendant knew, and continues to know, that its disclosures to the public and Plaintiffs were and are incomplete and misleading; and that Defendant's BHR resurfacing products were and are causing numerous patients severe injuries and complications. Smith & Nephew suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

369. As a result, Smith & Nephew actively and intentionally misled and continues to mislead the public, including the medical community, health care providers, and patients, into believing that the Defendant's BHR resurfacing products were and are safe and effective, leading to the prescription for and implantation of the BHR resurfacing products into patients such as

Plaintiffs. For example, in its 2015 annual report to the FDA, Smith & Nephew still did not list female patients or smaller bearing sizes in its list of contraindications for the BHR system, even though numerous studies cited those patient groups as being particularly at risk of premature failure.

370. Smith & Nephew failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Defendant's BHR resurfacing products. As compared to Smith & Nephew's BHR resurfacing products, feasible and suitable alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the hip joint and similar other conditions have existed at all times relevant.

371. Smith & Nephew's BHR resurfacing products were at all times utilized and implanted in a manner foreseeable to Defendant. Smith & Nephew failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing Defendant's BHR resurfacing products, thereby increasing the sales of the BHR resurfacing products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs and other patients who are female, or who have small femoral head sizes.

372. It was the duty of Defendant, Smith & Nephew, Inc. to comply with the Act, and the regulations promulgated pursuant to it, as well as the conditions established in the Approval Order with which Defendant agreed to comply in order to obtain premarket approval of its device. Yet, notwithstanding this duty, Defendant, Smith & Nephew, Inc. violated the Act as described in detail above.

373. Subsequently, the BHR systems implanted in Plaintiffs' hip failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by

Plaintiffs, as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

374. Under Alabama law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

375. Under Alaska law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act and protect others from unreasonable risks as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

376. Under Arizona law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

377. Under Arkansas law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

378. Under California law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

379. Under Colorado law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

380. Under Connecticut, law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

381. Under Delaware law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

382. Under District of Columbia law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

383. Under Florida law, Smith & Nephew owed a foreseeable duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

384. Under Georgia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

385. Under Hawaii law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty by failing to comply in the varying manner described above. The breach of such duty caused the Plaintiffs' injuries as described herein.

386. Under Idaho law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

387. Under Illinois law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

388. Under Indiana law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

389. Under Iowa law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

390. Under Kansas law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

391. Under Kentucky law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty was the actual, legal cause of the Plaintiffs' injuries as described herein.

392. Under Louisiana law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant failed to conform its conduct to the appropriate standard. The Defendant's substandard conduct was a breach of its duty. The breach of this duty caused the Plaintiffs' injuries as described herein.

393. Under Maine law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

394. Under Maryland law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

395. Under Massachusetts law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

396. Under Michigan law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act, as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

397. Under Minnesota law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act as a reasonable device manufacturer would and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

398. Under Mississippi law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

399. Under Missouri law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described

above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

400. Under Montana law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

401. Under Nebraska law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

402. Under Nevada law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

403. Under New Hampshire law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

404. Under New Jersey law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

405. Under New Mexico law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

406. Under New York law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

407. Under North Carolina law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

408. Under North Dakota law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

409. Under Ohio law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

410. Under Oklahoma law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described

above, and Defendant breached that duty. The breach of such duty caused the Plaintiffs' injuries as described herein.

411. Under Oregon law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendant's lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

412. Under Pennsylvania law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

413. Under Rhode Island law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

414. Under South Carolina law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

415. Under the laws of South Dakota, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

416. Under Tennessee law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendant's lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

417. Under Texas, law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendant's lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

418. Under Utah law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

419. Under Vermont law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

420. Under Virginia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

421. Under Washington law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

422. Under West Virginia law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendant's lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

423. Under Wisconsin law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty by failing to comply. Plaintiffs are within the class of individuals that could be injured by Defendant's lack of compliance. The breach of such duty was the actual and proximate cause of the Plaintiffs' injuries as described herein.

424. Under Wyoming law, Smith & Nephew owed a foreseeable, legal duty to Plaintiffs to comply with the act and prevent exposing plaintiffs to an unreasonable risk of harm as described above, and Defendant breached that duty. The breach of such duty was the proximate cause of the Plaintiffs' injuries as described herein.

425. Under the above states' laws, Smith & Nephew's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence.

426. Thus, under state's laws, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product

proximately causing injuries, and there is no need for the above states Legislatures to act in order to create such a remedy.

427. These states' law treats violations of federal statutes and regulations, among other things, as evidence of common law negligence.

428. Defendant also undertook a duty under the above states' law to comply with the terms of the PMA and to truthfully communicate safety information about the BHR.

429. In addition to the details set forth above, Smith & Nephew breached its duties under the above states' laws by:

a. manufacturing actual BHR Resurfacing products that differ from the specifications set forth in the CPMA, its Supplements, the Conditions of Approval and/or other federal regulations;

b. failing to manufacture the BHR product in compliance with FDA-approved specifications in the PMA;

c. failing to correctly monitor its products to ensure that it complied with appropriate quality control procedures and to track nonconforming products;

d. failing to conduct regular risk analysis of its BHR Resurfacing product, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes and failing to exercise appropriate post-market quality controls;

e. failing to provide the FDA with timely post-approval reports for its six month, one year, eighteen month, and two-year report schedules;

f. failing to comply with applicable federal and state regulations;

g. failing to monitor the sale and use of the BHR System; discover defects associated with the BHR System's use; and warn the government, doctors, and users about those defects;

h. failing to adequately train Defendant's employees who provided recommendations and advice to physicians who implanted the device;

i. failing to comply with the terms of the PMA;

j. failing to recall the BHR before September 2015;

k. failing to provide truthful and accurate information in its voluntary statements to the medical community outside the labeling;

l. failing to update the medical community as it learned of new or additional risks;

m. failing to update the medical community with information about the real-world survivorship rate of the BHR, government actions about monitoring metal ion levels, and similarity between the BHR and other MOM devices after originally providing this information to the medical community through advertisements and Dear Doctor letters as reproduced above;

n. failing to update patients with information about the real-world survivorship rate of the BHR, government actions about monitoring metal ion levels, and similarity between the BHR and other MOM devices after originally providing this information through marketing materials, websites and other direct-to-consumer statements; and

o. failing to properly train and educate physicians on the use of the BHR Resurfacing product, Defendant accepted a duty even to the Plaintiffs' physicians to train them to implant the BHR device correctly, and defendant did not fulfil their duty to

provide all necessary information to physicians. These claims are not expressly or impliedly preempted as Smith & Nephew voluntarily agreed to accept this duty to train physicians.

430. These simple common law negligence duties are parallel to the duties under federal law, and are not preempted by any federal law.

431. Smith & Nephew's breach of these duties caused Plaintiffs' injuries.

432. Defendant also made false, inaccurate and misleading statements concerning the properties and effects of the BHR Resurfacing product.

433. Smith & Nephew for years made voluntary statements outside the labeling and directly to patients, including Plaintiffs, that the BHR was safe. This message was delivered explicitly and implicitly, was designed to convey that the BHR was safe, went beyond mere descriptive puffery and was a material factor in patients choosing a BHR and/or choosing to agree to their doctor's recommendation (which was also secured by Smith & Nephew through false and misleading representations beyond the FDA-approved labeling) to undergo hip replacement surgery using a BHR.

434. Had Smith & Nephew been truthful in its statements to patients, and included material information that it actually omitted, patients would not have chosen the BHR and would have chosen a safer option, including but not limited to total hip replacement devices and/or total hip replacement devices using ceramic materials.

435. Smith & Nephew made voluntary statements outside the FDA-approved labeling to surgeons and the medical community about the safety of the BHR. These statements both explicitly and implicitly conveyed the message the BHR was safer, was safer than other metal-on-metal devices, was safer than total hip replacement, and was safer than ceramic hip devices. None

of those statements were true, and had Smith & Nephew made true statements and included material information that it had omitted regarding the safety of the BHR, surgeons would not have recommended to their patients, including Plaintiffs, that they undergo hip replacement using the BHR. Further, Smith & Nephew provided information from sources that, over time, published new and updated information. Smith & Nephew failed to provide this new and updated information which cast doubt or definitively proved that the BHR and all metal-on-metal hips was not safe. All of these voluntary statements and representations went beyond the information included in the FDA-approved labeling.

436. Defendant disseminated this false information, as referenced above, to physicians, the medical community, and the public with the intention to deceive physicians and their patients and to induce the physicians to prescribe the BHR Resurfacing product. These misrepresentations violated Defendant's obligations pursuant to 21 C.F.R. § 201.6(a).

437. Plaintiffs and/or Plaintiffs' physicians did in fact reasonably rely on Defendant's negligent misrepresentations, as Defendant intended. Specifically, Plaintiffs would have never had the BHR Resurfacing product implanted had they been aware of the falsity of the representations specifically delineated in the preceding paragraphs

438. Defendant knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above.

439. Had Defendant exercised ordinary care, and complied with the then existing standards of care, Plaintiffs would not have been injured.

COUNT III
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

440. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

441. Smith & Nephew designed, manufactured, inspected, labeled, leased, distributed, marketed, sold, and otherwise released the BHR resurfacing product the into the stream of commerce.

442. In doing so, Defendant directly advertised or marketed the BHR resurfacing product to the FDA, health care professionals, and consumers or persons responsible for consumers.

443. Defendant thus had a duty to warn of the risks associated with the device.

444. Defendant failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, about the true risks of the BHR resurfacing product, including that the device would:

a. Fail at a much higher rate than suggested;
b. Increase a plaintiffs' blood content of chromium and cobalt to exceedingly high and dangerous levels;
c. Cause metallosis, despite being aware of the risk of metallosis as early as 2006;
d. Fail to work, entirely, with female patients, which would later become the subject of a full recall and contraindication.

445. Moreover, Defendant failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, about the true risks of the BHR resurfacing product, by:

a. Failing to adequately train physicians on the requisite technique required to implant the BHR device, a duty voluntarily assumed by Smith & Nephew. Smith & Nephew's own warning label advises that only physicians with the proper training should implant the BHR product; Defendant also indicates that physicians should "contact Smith & Nephew for the BHR surgical technique manual and procedural training protocol."

b. Failing to adequately report post-market adverse events to the FDA when known, as required by 21 C.F.R. § 803.50(a);

c. Failing to report new clinical investigations and studies that concern the BHR product as required by 21 C.F.R. 814.84(b)(2);

d. Failing to use the Changes Being Effected process to update medical professionals in compliance with FDA directives.

446. Upon obtaining knowledge of these potential device failure modes, the Defendant was required under the BHR PMA, 21 CFR §§820.30 et seq., 21 CFR §§ 820.100 et seq. and the FDA Recognized Consensus Standard ISO 14971 to use this information to routinely update the risk analyses for the BHR device and take any and all Corrective Action and Preventative Actions ("CAPA") necessary to address non-conformance and other internal quality control issues. Furthermore, Defendant was required to establish Quality Management Systems ("QMS") procedures to assess potential causes of non-conforming products and other quality problems with the products, such as latent manufacturing defects. 21 CFR §§ 820.70 et seq.; 21 CFR §§ 820.30 et seq.

447. Defendant's conduct violated these regulations and also separately violated its duties under the follow state law, thereby jeopardizing the health of patients, including Plaintiffs.

448. Had Defendant provided timely and reasonable warnings regarding the safety and efficacy of the BHR resurfacing product, those warnings would have been heeded and no healthcare professional, including Plaintiffs' physicians, would have used the BHR resurfacing product and no patient or consumer, including Plaintiffs, would have allowed use of the device. Defendant's failure to provide timely and reasonable warnings, instructions, and information regarding the BHR resurfacing product rendered the device unreasonably dangerous and defective.

449. As a direct and proximate result of Defendant's actions, omissions, and misrepresentations, Plaintiffs suffered injury, including elevated metal ion levels, device failure and additional surgical procedures to repair and/or remove their BHR implant for replacement with another, safer hip replacement device. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the BHR resurfacing product. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

COUNT IV
NEGLIGENT FAILURE TO WARN CLAIMS

450. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

451. The individual states' common tort laws recognize that a duty to warn forms the basis of a negligence case in a products liability action.

452. Defendant in their conduct herein has violated duties imposed by individual states that require a duty to warn on manufacturers if the item it produces has an inherent and hidden danger about which the producer knows or should know, could be a substantial factor in bringing injury to an individual.

453. The individual states' duty to warn violated by the defendant extends beyond the time of sale and requires the defendant manufacturer to make reasonable efforts to convey an effective warning which include warning to third parties such as the FDA.

454. Defendant learned new information about the BHR safety risks, yet failed to make reasonable efforts to issue an effective post-sale warning.

455. These state-based violations of duty to warn parallel federal duties imposed by the PMA including but not limited to the duty to provide the FDA with "Adverse Reaction: and "Device Defect" reports (Approval Order attach 1, Conditions of Approval. at 29, citing 21 C.F.R. §814.82(a)(9))). Under the Medical Device Reporting Regulation, Defendant has a duty to "report to the FDA whenever [manufacturers] receive or otherwise become device marketed by the manufacturers] receive or otherwise become aware of information …. That reasonably suggests that a device marketed by the manufacturer…[m]ay have caused or contributed to a death or serious injury."

456. The state-based failure to warn claims herein parallel Smith & Nephew's failure to comply with FDA requirements under the MDA and CGMPs to make certain reports and disclosures to the FDA, and these failures caused Plaintiffs' injuries.

COUNT V
NEGLIGENT MISREPRESENTATION CLAIMS

457. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

458. Defendant had a duty under the laws of the individual states and a parallel federal duty as described above to accurately and truthfully represent to the FDA, medical community, Plaintiffs, and the public the facts about the safety of the BHR. Instead, the representations made by Defendant were false, misleading, omitted material information or otherwise left a false impression about the safety of the BHR as described in detail above.

459. Smith & Nephew consistently under-reported and withheld information about the likelihood of the BHR to fail and cause injury and complications, and has misrepresented the efficacy and safety of the BHR resurfacing products, actively misleading the FDA, medical community, patients, the public at large, and Plaintiffs.

460. Defendant knew, and continues to know, that its disclosures to the public (including statements made outside the labeling) and Plaintiffs were and are incomplete and misleading and that Defendant's BHR resurfacing products were and are causing numerous patients severe injuries and complications. Smith & Nephew suppressed this information, and failed to accurately and completely disseminate or share this and other critical information with the medical community, health care providers, and patients.

461. As a result, Smith & Nephew, through its voluntary statements made outside the labeling as described in detail above, negligently misled and continues to mislead the public, including the medical community, health care providers, and patients, into believing that the Defendant's BHR resurfacing products were and are safe and effective, leading to the prescription for and implantation of the BHR resurfacing products into patients such as Plaintiffs.

462. Smith & Nephew failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of Defendant's BHR resurfacing products. As compared to Smith & Nephew's BHR resurfacing products, feasible and suitable

alternative designs, procedures, and instruments for implantation and treatment of damaged and worn parts of the hip joint and similar other conditions have existed at all times relevant.

463. Smith & Nephew's BHR resurfacing products were at all times utilized and implanted in a manner foreseeable to Defendant. Smith & Nephew failed to warn and provided incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing Defendant's BHR resurfacing products, thereby increasing the sales of the BHR resurfacing products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiffs and other patients who are female, or who have small femoral head sizes.

464. Smith & Nephew's failure to comply with the above-stated duties is evident through the non-exhaustive facts detailed above of malfeasance, misfeasance, and/or nonfeasance on the part of Defendant. Subsequently, the BHR system implanted in Plaintiffs' hips failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs, as defined in 21 C.F.R. § 803.3. As a direct and proximate result, Plaintiffs endured pain and suffering and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; both past and future non-economic damages including, but not limited to, physical and mental pain and suffering, inconvenience, emotional distress and impairment of the quality of his life; and permanent impairment and disfigurement.

465. Plaintiffs are pursuing this parallel state common law claim for negligent misrepresentation based upon Smith & Nephew's violations of the applicable federal regulations as described above, or based on acts and omissions by Smith & Nephew that are not explicitly or impliedly preempted by federal law.

466. Prior to, on, and after the date the devices were implanted in Plaintiffs, and at all relevant times, Defendant negligently and carelessly represented to Plaintiffs, their health care providers, and the general public that certain material facts were true.

467. The representations include, in addition to the detailed allegations above, the following:

a. That the BHR products were safe, fit, and effective for use, and were in fact, superior to a full hip replacement for patients;

b. That the BHR products were "a conservative approach to hip arthroplasty" that was safer and more effective than a total hip arthroplasty;

c. That the features of the BHR products included:

i. Less bone resection than conventional total hip arthroplasty;

ii. The success rate was supported by the availability of global, long-term clinical outcomes data

iii. That the BHR featured "[f]unctionally optimized metallurgy and design."

d. That the BHR products were safer and more effective than other available metal hip replacements on the market;

e. That the BHR products post-market were not found to have any increased risks of device failures or complications, and enjoyed a "survival" rate as high as 94.4 percent over ten years;

f. That the BHR was safe.

468. In addition to the numerous representations mentioned above, as late as in its 2015 annual report to the FDA, Smith & Nephew still did not list female patients or smaller bearing sizes in its list of contraindications for the BHR system, even though numerous studies cited those patient groups as being particularly at risk of premature failure.

469. These misrepresentations, among others alleged herein, were made by Defendant with the intent to induce Plaintiffs and their physicians to prescribe and implant the BHR product.

470. At the time of Defendant's misrepresentations and omissions, Plaintiffs and their physicians were ignorant of the falsity of the statements and believed them to be true.

471. Prior to, on, and after the dates during which Plaintiffs and their physicians purchased and used the device, said representations were not true, and there was no reasonable ground for believing said representations to be true at the times said representations were made.

472. All of the aforementioned information and representations emanated from the same source, Smith &Nephew, and was vetted by its copy review department (or equivalent) to ensure uniformity and harmony of the marketing message. The manner by which such information and representations were distributed, made available, or otherwise provided by Smith & Nephew to Plaintiffs and their health care providers was the same and include, but are not limited to, the following: reports, press releases, advertising campaigns, product information, instructions for use and other labeling materials provided with the BHR products, print advertisements, commercial media containing material representations, as well as through their officers, directors, agents and representatives, including the Smith & Nephew sales representatives that met with, detailed, and instructed Plaintiffs prescribing and implanting physicians on the BHR resurfacing products, the applications and reports by Smith &Nephew to the FDA for the BHR products, patient brochures, training seminars hosted by said Defendant, CME materials created and distributed by Smith &Nephew, information supplied at professional conferences at booths hosted or manned by Smith &Nephew, or their Key Opinion Leaders, as well as the websites of Smith &Nephew that provided information on the BHR resurfacing products including product description, indications for use, instructions for use, and ordering information.

473. Prior to, on, and after the dates Plaintiffs and their physicians purchased and used the BHR resurfacing products, said representations were untrue at the times they were made, and

there was no reasonable ground for Smith &Nephew to believe said representations were true when said Smith &Nephew made said representations. And to the extent Smith & Nephew did not know representations were untrue, when Smith & Nephew learned the representations were not true, it failed to correct the record and update the medical community on the truth, leaving a false impression about the safety of the BHR due to Smith & Nephew's failures to communicate.

474. Prior to, on, and after the dates Plaintiffs' and their physicians purchased and used the BHR resurfacing products, Smith &Nephew intended that Plaintiffs' and their physicians, and the general public would rely on said representations and prescribe and implant the BHR resurfacing products, which did in fact occur.

475. Prior to, on, and after the dates during which BHR resurfacing products purchased and used the device, Smith & Nephew intended that Plaintiffs, their physicians, and the general public would rely on said representations, which did in fact occur.

476. Smith & Nephew knew or should have known prior to introduction on the market and at the time of submitting its PMA applications that these representations were untrue, from their own internal testing, analysis and investigation throughout the design and manufacturing process.

477. Moreover, post-market performance promptly revealed poor outcomes in patients who were suffering failures and adverse events at an increased rate compared to other hip replacement devices. This triggered the obligation for further investigation and analysis of the safety and efficacy of the Birmingham Hip Resurfacing product from Smith & Nephew, which further confirmed that the Birmingham Hip Resurfacing products were, in fact, inferior in safety and efficacy and posed greater risks of harm and death than other hip replacement products on the market.

478. It was known or should have been known by Smith &Nephew, at all relevant times, that the BHR products, by way of their less invasive design, created and caused these devices to be more apt to fail; indeed, BHR resurfacing products were found to occur at a significantly increased rate compared to other Hip replacement products. This information was revealed in said Defendant's pre-market testing and analysis, and has been reaffirmed throughout the post-market experience of these products, as reflected by the increased number of these adverse event reports by physicians and published opinions in medical literature.

479. Smith & Nephew owed a duty in all their undertakings, including the dissemination of information concerning its BHR resurfacing products, to exercise reasonable care to ensure that they did not in those undertakings create unreasonable risks of personal injury to others.

480. As set forth above Smith & Nephew disseminated to health care professionals and consumers through published labels, labeling, marketing materials, and otherwise information concerning the properties and effects of Birmingham Hip Resurfacing device with the intention that health care professionals and consumers would rely upon that information in their decisions concerning whether to prescribe and use Defendant's BHR resurfacing products.

481. Smith & Nephew, as a medical device designer, manufacturer, seller, promoter and/or distributor, knew or should reasonably have known that health care professionals and consumers, in weighing the potential benefits and potential risks of prescribing or using BHR resurfacing products, would rely upon information disseminated and marketed by Defendant to them regarding the BHR resurfacing products, including information outside the labeling.

482. Smith & Nephew failed to exercise reasonable care to ensure that the information they disseminated to health care professionals and consumers concerning the properties and effects of Birmingham Hip Resurfacing device was accurate, complete, and not misleading and, as a

result, disseminated information to health care professionals and consumers that was negligently and materially inaccurate, misleading, false, and unreasonably dangerous to consumers such as Plaintiffs.

483. Smith & Nephew, as a medical device designer, manufacturer, seller, promoter and/or distributor, also knew or reasonably should have known that patients receiving Birmingham Hip Resurfacing device as recommended by health care professionals in reliance upon information disseminated by Defendant as the manufacturer/distributor of Defendant's BHR resurfacing products would be placed in peril of developing the serious, life-threatening, and life-long injuries including, but not limited to, metallosis, increased chromium and cobalt levels, and additional surgery.

484. Smith & Nephew had a duty to promptly correct material misstatements Defendant knew others were relying upon in making healthcare decisions. Defendant purposely chose not to, however, in order to maintain their market share and level of competition with other hip device manufacturers.

485. Defendant failed in each of these duties by misrepresenting to Plaintiffs, their implanting physicians, and the medical community in general, the safety and efficacy of Birmingham Hip Resurfacing device and failing to correct known misstatements and misrepresentations.

486. In sum, Smith & Nephew for years made voluntary statements outside the labeling and directly to patients, including Plaintiffs, that the BHR was safe. This message was delivered explicitly and implicitly, was designed to convey that the BHR was safe, went beyond mere descriptive puffery and was a material factor in patients choosing a BHR and/or choosing to agree to their doctor's recommendation (which was also secured by Smith & Nephew through false and

misleading representations beyond the FDA-approved labeling) to undergo hip replacement surgery using a BHR.

487. Had Smith & Nephew been truthful in its statements to patients, and included material information that it actually omitted, patients would not have chosen the BHR and would have chosen a safer option, including but not limited to total hip replacement devices and/or total hip replacement devices using ceramic materials.

488. Smith & Nephew made voluntary statements outside the FDA-approved labeling to surgeons and the medical community about the safety of the BHR. These statements both explicitly and implicitly conveyed the message the BHR was safer, was safer than other metal-on-metal devices, was safer than total hip replacement, and was safer than ceramic hip devices. None of those statements were true, and had Smith & Nephew made true statements and included material information that it had omitted regarding the safety of the BHR, surgeons would not have recommended to their patients, including Plaintiffs, that they undergo hip replacement using the BHR. Further, Smith & Nephew provided information from sources that, over time, published new and updated information. Smith & Nephew failed to provide this new and updated information which cast doubt or definitively proved that the BHR and all metal-on-metal hips was not safe. All of these voluntary statements and representations went beyond the information included in the FDA-approved labeling.

489. As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

COUNT VI
NEGLIGENCE PER SE

490. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

491. Defendant had a duty to exercise reasonable care and comply with existing standards in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of BHR Resurfacing product, and post-market vigilance regarding same, and to comply with the terms of the PMA.

492. Defendant failed to exercise reasonable care and failed to comply with existing laws in the researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, labeling and/or distribution of the BHR Resurfacing product, and post-market vigilance regarding same, and by failing to comply with the terms of the PMA.

493. Under federal law governing labeling for the BHR Resurfacing product, Defendant was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e) (amended and recodified on June 30, 2006 at 21 C.F.R. § 201.80(e)), for devices approved before June 30, 2001, including The BHR Resurfacing product). Defendant also was required to list adverse reactions that occurred with other products in the same class as the BHR Resurfacing product. *Id.* at § 201.57(g) (re-codified on June 30, 2006 at 21 C.F.R. § 201.80(g), for drugs approved before June 30, 2001). Breaches of these duties constitute independent acts of negligence under state law.

494. Defendant failed to exercise reasonable care and violated 21 U.S.C. §§ 331, 352; 42 U.S.C. § 1320a-7b, and 21 C.F.R. §§ 201.57, 201.80, and 201.128, in particular. The violations constitute independent violations of state negligence law.

495. The BHR was misbranded under federal law as described above.

496. The laws, regulations and terms of the PMA violated by Defendant were designed to protect Plaintiffs and similarly situated persons and protect against the risks and hazards that have actualized in this case. Therefore, Defendant's conduct constitutes negligence per se.

497. Defendant knew or should have known that consumers, such as Plaintiffs and their minor children, would foreseeably suffer injury as a result of Defendant's failures to exercise reasonable care, as set forth above.

498. Defendant's negligence was the proximate cause of Plaintiffs' harm, and economic loss, which Plaintiffs suffered and/or will continue to suffer.

499. As a direct and proximate result of the foregoing acts and omissions, Plaintiffs suffered physical pain, additional surgeries, mental anguish, and diminished enjoyment of life, and will require lifelong medical treatment, monitoring and/or medications.

COUNT VII
BREACH OF EXPRESS WARRANTIES

500. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

501. Smith & Nephew warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the BHR resurfacing products were of merchantable quality, fit for the ordinary purposes and uses for which it was sold.

502. Smith & Nephew expressly warranted to Plaintiffs, by and through its authorized agents or sales representatives, in publications, package inserts, the internet, and other communications intended for Plaintiffs' physicians, patients, Plaintiffs, and the general public, that the system was safe, effective, fit and proper for its intended use.

503. Smith & Nephew is aware that health care providers and patients, including the Plaintiffs, rely upon the representations made by the Defendant when choosing, selecting and purchasing its products, including the BHR resurfacing products.

504. Due to the defective and unreasonably dangerous BHR resurfacing products, it was neither of merchantable quality nor fit for the particular purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Plaintiffs, during foreseeable use.

505. Defendant breached their warranty of the mechanical soundness of the BHR system by continuing sales and marketing campaigns highlighting the safety and efficacy of its product, while Defendant knew or should have known of the defects and risk of product failure and resulting patient injuries.

506. Defendant made numerous claims to the general public, and to Plaintiffs in particular, that the BHR devices were safe for their intended use and that they did not suffer from the same problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary. For example, in 2012, Defendant's senior vice president publicly touted the BHR as being "unlike any other metal-on-metal hip implant" with a survivorship rate superior to even traditional non-metal devices due to its "distinctive metallurgy heritage" and other factors.

507. Instead of warning patients about the dangers of metal toxicity, which were well documented even in 2006 when the BHR was approved, Smith & Nephew as recently as 2013 disseminated unpublished reports from its own design surgeon, Derek McMinn, stating that "there does not appear to be any conclusive evidence that elevated cobalt and chromium levels have any significant detrimental effects in total hip arthroplasty patients." As recently as January, 2015, Defendant referred patients with questions about the BHR devices to a website, www.surfacehippy.com, with claims about people with the BHR devices who completed extraordinary physical feats after implantation, including a "sprint triathlon" with their prosthetic BHR devices. The same website, where Smith & Nephew prominently advertises its BHR device,

publishes misleading articles by orthopedic surgeons and paid consultants, including but not limited to the BHR designer, Dr. Derek McMinn, downplaying the risks of the failure-prone BHR device, and comparing them favorably to other metal-on-metal devices, even though the BHR is just as failure prone as some of these other devices, according to clinical studies.

508. Smith & Nephew enlisted the services of professional athletes and celebrities in its efforts to promote the BHR system, including former NHL hockey player Tim Taylor, former NFL quarterback Steve Beuerlein, and former professional cyclist Floyd Landis. The most recent example of these misleading marketing efforts is a campaign by Dr. McMinn himself, modeled after the presidential campaign slogan of Donald Trump, to "Make Resurfacing Great Again," through the use of a safer resurfacing device that includes a polyethylene acetabular cup, the PHR, which purportedly avoids the problems associated with metal-on-metal articulation in the original BHR system. Thus, despite an overwhelming body of clinical literature showing the dangers of cobalt and chromium toxicity, the BHR's inventor and spokesman continues even today to blame patient "allergy sufferers," rather than the manufacturer or himself, for widespread metal-on-metal injuries. Dr. McMinn also is calling on Smith & Nephew to reverse the recall for women and patients with smaller joint sizes, claiming in an online petition that Smith & Nephew failed to consult with him before issuing the recall. McMinn's petition asks Smith & Nephew to put the recalled device back on the U.S. market but only make it available to surgeons such as himself instead of American doctors, some of whom he calls "trainee surgeons."

Friday 20th January 2017 Make Resurfacing Great Again!

This InaugurationDay, Mr McMinn says *'Make Resurfacing Great Again'*, pictured here with Joseph Daniel (McMinn Centre Director of Research) and Terry Smith (Managing Director of Jointmedica).

(Left to Right: Joseph Daniel, Mr Derek McMinn & Terry Smith)

Mr McMinn's latest invention, the Metal-on-Polyethylene PolyMotion® Hip Resurfacing device is now available on a custom basis, click here for more information. The PHR is an ideal solution for metal allergy sufferers who want to reap the same rewards as a standard Hip Resurfacing. For further information, please watch Mr McMinn's latest video lecture available here.

509. Pursuant to 21 U.S.C. § 360k, the above statements constitute a violation of the PMA because the FDA's conditional approval of the BHR devices warned Defendant that its "warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State Laws."

510. Defendant also made numerous claims to the general public, and in particular, directly to and which were actually received by Plaintiffs (and directly to their physicians), that the BHR devices were safe for their intended use and that they did not suffer from the same

problems that plague other metal-on-metal hips, even though it was in possession of information to the contrary.

511. These claims are described above by way of example and include, but are not limited to, the websites, patient marketing materials, Apples to Oranges marketing materials and Dear Doctor letters described above. Further discovery will produce additional similarly misleading marketing materials.

512. Defendant breached their warranty of the mechanical soundness of the BHR system by continuing sales and marketing campaigns highlighting the safety and efficacy of its product, while Defendant knew or should have known of the defects and risk of product failure and resulting patient injuries.

513. Under Alabama law, Code of Alabama § 7-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

514. Under Alaska law, Alaska Statute § 45.02.313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

515. Under Arizona law, Arizona Revised Statute § 45.02.313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

516. Under Arkansas Law, Arkansas Code Annotated § 85-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

517. Under California Law, California Commercial Code § 2313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

518. Under Colorado Law, Colorado Revised Statute 4-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed

would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

519. Under Connecticut Law, Connecticut General Statute § 42a-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

520. Under Delaware Law, 6 Delaware Code § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

521. Under District of Columbia Laws, District of Columbia Code § 28:2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

522. Under Florida Law, Florida Annotated Statute § 672.313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly

warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

523. Under Georgia Law, Georgia Annotated Code § 11-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

524. Under Hawaii Law, Hawaii Revised Statute § 490:2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

525. Under Idaho Law, Idaho Code § 28-2313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

526. Under Illinois Law, 810 Illinois Compiled Statutes Annotated 5/2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product

was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

527. Under Indiana Law, Indiana Code Annotated § 26-1-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

528. Under Iowa Law, Iowa Code § 554.2313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

529. Under Kansas Law, Kansas Statute Annotated § 84-2,313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

530. Under Kentucky Law, Kentucky Revised Statutes § 355.2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

531. Under Louisiana Law, from *Fields v. Walpole Tire Serv., L.L.C.*, 37 So. 3d 549, 552 (La. Ct. App. 2010), Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

532. Under Maine Law, Maine Revises Statute Title 11, § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

533. Under Maryland Law, Maryland Commercial Law Code Annotated § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR

product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

534. Under Massachusetts Law, Annotated Laws of Massachusetts GL ch. 106, § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

535. Under Michigan Law, Michigan Compiled Laws Service § 440.2313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

536. Under Minnesota Law, Minnesota Statute § 336.2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

537. Under Mississippi Law, Mississippi Code Annotated § 75-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly

warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

538. Under Missouri Law, § 400.2-313 Revised Statute Missouri, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

539. Under Montana Law, 30-2-313 Montana Code Annotated, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

540. Under Nebraska Law, Revised Statutes of Nebraska § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

541. Under Nevada Law, Nevada Revised Statute Annotated § 104.2313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product

was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

542. Under New Hampshire Law, Revised Statute Annotated 382-A:2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

543. Under New Jersey Law, New Jersey Statute § 12A:2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

544. Under New Mexico Law, New Mexico Statute Annotated § 55-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

545. Under New York Law, New York Consolidated Laws Service Uniform Commercial Code § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

546. Under North Carolina Law, North Carolina General Statute § 25-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

547. Under North Dakota Law, North Dakota Century Code § 41-02-30, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

548. Under Ohio Law, Ohio Revised Code Annotated 1302.26, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed

would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

549. Under Oklahoma Law, 12A Oklahoma Statute § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

550. Under Oregon Law, Oregon Revised Statute § 72.3130, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

551. Under Pennsylvania Law, 13 Pennsylvania Consolidated Statutes § 2313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

552. Under Rhode Island Law, Rhode Island General Laws § 6A-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements,

expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

553. Under South Carolina Law, South Carolina Code Annotated § 36-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

554. Under South Dakota Law, South Dakota Codified Laws § 57A-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

555. Under Tennessee Law, Tennessee Code Annotated § 47-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

556. Under Texas Law, Texas Business and Commerce Code § 2.313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe

and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

557. Under Utah Law, Utah Code Annotated § 70A-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

558. Under Vermont Law, Vermont Statutes Annotated § 2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

559. Under Virginia Law, Virginia Code Annotated § 8.2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

560. Under Washington Law, Revised Code Washington § 62A.2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

561. Under West Virginia Law, West Virginia Code § 46-2-313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

562. Under Wisconsin Law, Wisconsin Statute § 402.313, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

563. Under Wyoming Law, Wyoming Statute 34-21-230, Smith & Nephew expressly warranted, as described above and herein, directly to Plaintiffs that the product was safe and effective for use when it was not. Smith & Nephew, through its own statements, expressly warranted that the BHR product was safe and effective and that the BHR product when distributed

would conform to that express affirmation, and Plaintiffs (and their physicians) relied on those express affirmations in their decision to use the BHR.

564. The defective and unreasonably dangerous condition of the BHR products constituted a breach of the Defendant's express warranties under state law.

565. The above-mentioned violations and failures constitute a parallel violation of state common law and statutory law that predates and operates independently from the above federal requirements.

566. As a direct and proximate result of Defendant's breaches of express warranties, Plaintiffs have sustained severe damages and injuries as described elsewhere in this Complaint, including metallosis, tissue damage and necrosis, revision surgery, exposure to toxic levels of chromium and cobalt ions in his body, and unknown long-term consequences that continue to this day and into the future. He has further suffered past and future medical expenses, past and future wage loss; physical pain and suffering, both past and future; mental anguish and emotional distress.

COUNT VIII
MANUFACTURING DEFECT

567. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

568. Smith & Nephew manufactured, distributed, and/or sold the BHR System, including the acetabular cups and femoral heads, that were implanted in Plaintiffs' hip joints and failed.

569. At the time Smith & Nephew manufactured, distributed, and/or sold the BHR System, including the acetabular cup and femoral head, that was implanted in Plaintiffs' hip joints, it was required to comply with the FDA's Quality Systems Regulations ("QSR"), 21 C.F.R. § 820

et seq. Smith & Nephew's failure to follow these regulations was a cause of the manufacturing defect in the BHR System implanted in Plaintiffs' body.

570. Smith & Nephew violated the CGMP requirements when it failed to do the following:

a. Govern the manufacturing methods used to manufacture, produce and distribute the BHR;

b. Failed to govern the manufacturing facilities and the quality controls used for the design, manufacture, packaging, labeling, storage, installation and servicing of all finished BHR systems;

c. Failed to adopt procedures and controls relating to design control; quality assurance; manufacturing and processing; process validation; device inspection and corrective and preventive action.

d. Failed to ensure that the initial specifications for hardness, radial clearance, sphericity, wall thickness and surface roughness were followed during the manufacturing process.

571. Smith & Nephew further violated FDA-required manufacturing specifications when it failed to manufacture the BHR system Plaintiffs received in a way that was consistent with the FDA premarket approval specifications, as required by 21 C.F.R. § 814.80.

572. As a further direct and proximate result of Smith & Nephew's above cited violations, the BHR system implanted in Plaintiffs was manufactured with material that did not meet the FDA's requirements for hardness, durability, surface roughness, composition, and finish.

573. The duty of a manufacturer to use due care in manufacturing a medical device predates the Medical Device Amendments, and is a duty that Smith & Nephew owes to Plaintiffs. This theory of manufacturing defect is therefore not impliedly preempted by federal law, nor is it expressly preempted as the duty is one of state tort law which is parallel to the federal requirement that the BHR System be manufactured according to the approved specifications for the medical device.

574. In addition to the above requirements, the FDA's Quality Systems Regulations ("QSR") (21 CFR § 820 *et seq*) include the duty to identify and respond to a "nonconforming product." A manufacturer, such as Smith & Nephew, must "establish and maintain procedures to control product that does not conform to specified requirements," such as a failure to conform to performance and design standards set forth in the manufacturer's PMAs and supplements. 21 CFR § 820.90. "The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product." CGMP/QSR also require a manufacturer to establish and maintain procedures for implementing corrective actions and preventive actions ("CAPAs"), including investigating the cause of nonconformities in the product, processes and quality systems, and taking corrective action to prevent recurrence of such nonconformities. 21 CFR § 820.100.

575. FDA's CGMP/QSR may require a manufacturer to test for, monitor for (through post-marketing surveillance), discover, investigate and remedy issues related to the safe and effective use of a medical device as approved. A part of satisfying these post-marketing surveillance duties can be to formulate and then effectively execute a Postmarketing Surveillance Plan for the purpose of ascertaining any issues regarding the safe and effective use of the device once released to the market. 21 CFR § 822.8.

576. Similar to Postmarketing Surveillance Plans, CGMP/QSR require a manufacturer to review and evaluate all complaints regarding the operation of a medical device and determine whether an investigation is necessary. 21 CFR § 820.198(b).

577. An investigation must be completed when a complaint involves the possible failure of a device, its labeling or its packaging to meet any of its specifications, unless an investigation for a similar complaint has already been performed. 21 CFR § 820.198(c).

578. Also similar to Postmarketing Surveillance Plans, a device manufacturer is required to establish and maintain procedures to identify valid statistical techniques for establishing, controlling and verifying the acceptability of process capability and product characteristics, unless the manufacturer documents justification for not having procedures in place regarding statistical techniques. 21 CFR § 820.250 and 21 CFR § 820.1(a)(3).

579. A medical device manufacturer is required to comply with FDA requirements for records and reports, in order to prevent introduction into the market of medical devices that are adulterated or misbranded, and to assure the continued safety and effectiveness of a medical device.

580. In particular, a manufacturer must keep records and make reports if any medical device may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. 21 U.S.C. § 360i. "Serious injury" is defined to mean an injury that "necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure…." *Id.*

581. According to its Congressional mandate, the FDA must establish regulations requiring a manufacturer of a medical device to report promptly to the FDA any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. 21 U.S.C. § 360i.

582. Adverse events associated with a medical device must be reported to the FDA within 30 days after a manufacturer becomes aware that a device may have caused or contributed to death or "serious injury," or that a device has malfunctioned and would be likely to cause or contribute to death or "serious injury" if the malfunction was to recur. 21 CFR § 803.50(a).

583. This reporting is mandatory and is a condition of continued PMA approval. 21 CFR § 814.82. Such reports must contain all information reasonably known to a manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. 21 CFR § 803.50(b)(1).

584. Smith & Nephew failed to manufacture the BHR System with material that met the FDA's requirements for hardness, durability, composition, and finish, in violation of 21 C.F.R. § 814.80. This resulted in excessive edge loading and wear rates, due to manufacturing deviations in wall thickness, surface roughness, sphericity, and radial clearance as described in more detail above.

585. The BHR System implanted in Plaintiffs' bodies possessed a defect in its manufacture that existed when the device left Smith & Nephew's possession. As a result of this defect, the device did not conform to the design specifications for the BHR System approved by the FDA.

586. These defects include, but are not limited to, the above-mentioned deviations from the maximum clearance specified by Smith & Nephew for the femoral heads and acetabular cups for the BHR, and the resulting excessive linear wear rate for the BHR.

587. On information and belief, the ideal tolerances for clearance of the as-cast BHR device components were not met due to problems with the hardness of the metal and this caused too much or too little clearance, resulting in premature failure due to metallosis as described above.

588. On information and belief, the carbide volume of the metal was not controlled during manufacturing and therefore allowed for increased wear rates which resulted in premature failure due to metallosis and related causes.

589. On information and belief, the specific contents of the metal were not controlled between batches, which allowed differences in hardness levels between the cup and the femoral head of the BHR, resulting in increased risk of premature failure.

590. On information and belief, the manufacturing process employed by Defendant for their BHR product, including those implanted in Plaintiffs, resulted in surface damage to the metal of the femoral head and acetabular components, weakening the structural integrity of Defendant's BHR product, thus increasing the risk of scratches, dislocation, higher than expected linear wear, and "edge loading" which increases the risk of dislocation and elevated blood metal ion concentration, e.g., metallosis.

591. On information and belief, Defendant maintained design and manufacturing specifications that BHR resurfacing products were required to have the appropriate carbide volume of metal content, strength, size, durability, appearance, and resistance levels, and should not be distributed if they exhibited a certain degree of surface damage. The manufacturing process was intended to catch and identify any end-product BHR resurfacing products that did not meet specifications and not distribute said BHR products. But Defendant failed to identify BHR devices that were out of specification.

592. These manufacturing defects rendered the BHR device unreasonably dangerous to Plaintiffs.

593. The defect in manufacture was a cause of injury to Plaintiffs.

594. If Smith & Nephew had followed its own manufacturing specifications for clearance, hardness, and linear and volumetric wear, the premature failure of Plaintiffs' devices would not have occurred. The above manufacturing defects are evidence of implied negligence under the doctrine of *Res Ipsa Loquitur*.

595. As a direct and proximate result of Smith & Nephew's violation of federal statutory and regulatory standards of care, and specific state laws, as set forth below, a BHR system including the BHR Acetabular Cup and Femoral Head, was implanted in Plaintiffs and failed, and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs as defined in 21 C.F.R. 803.3. As a direct result, Plaintiffs endured pain and suffering and have required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; physical pain and suffering, both past and future mental anguish and emotional distress, both past and future, including, but not limited to, humiliation, embarrassment, annoyance and aggravation.

596. The Act contains an express preemption provision, 21 U.S.C. § 360(k), which in relevant part states: "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— (1) which is different from, or in addition to, any requirement applicable under this Act [21 USCS §§ 301, et seq.] to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act [21 USCS §§ 301, et seq.]."

597. This cause of action is based entirely on the contention that Smith & Nephew violated federal safety statutes and regulations. Plaintiffs do not bring the underlying action as an implied statutory cause of action, but rather they are pursuing parallel state law claim, pursuant to the state laws as set forth below, based upon Defendant, Smith & Nephew's violations of the applicable federal regulations.

598. Defendant is liable pursuant to the manufacturing defect common laws and statutory regimes of each state where Plaintiffs reside. Specifically, the Laws of Alabama

(pursuant to the Alabama Manufacturing Extended Liability Doctrine), Alaska, Arizona, California, Colorado, Florida, Hawaii, Idaho, Illinois, Indiana (pursuant to the I.C. 33-1-1.5-1, et seq., governing strict liability in Indiana, in addition to state law negligence claims), Iowa, Kansas, Kentucky, Louisiana, Maine (pursuant to Me. Rev. Stat. tit. 14, § 221, et seq., governing strict liability in Maine in addition to state law negligence claim), Maryland, Massachusetts, Michigan, Minnesota, Mississippi as set forth in the strict liability and negligence provisions of Miss. Code Ann. § 11-1-63), Missouri, Montana (pursuant to MCA § 27-1-719 governing strict liability in MT, in addition to state law negligence claims), Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota (pursuant to Chapter 28-01.1, et seq., N.D.C.C., the North Dakota Products Liability Act governing strict liability in ND, , in addition to state law negligence claims), Oklahoma , Oregon, (pursuant to Or. Rev. Stat. Ann. § 30.920, in addition to state law negligence claim), Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee (codification of common law negligence and strict liability in 29-28-192 (Tennessee Product Liability Act)), Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming for *per se* strict liability and common law Negligence.

599. Smith & Nephew's violations of the aforementioned federal safety statutes and regulations violate each states' product strict liability and negligence laws to the extent those laws relate to manufacturing defects.

600. Smith & Nephew was engaged in the business of selling the BHR system.

601. At the time the BHR Systems, including the Acetabular Cups and Femoral Heads, left the control of Defendant, they were unreasonably dangerous and not fit for foreseeable use, due to non-compliance with the Act, and/or because Smith & Nephew was negligent in not taking

reasonable measures in manufacturing its product against foreseeable risk, as set forth in detail above.

602. The BHR systems which left the control of Smith & Nephew were expected to and did reach Plaintiffs without a substantial change in condition. Specifically, the BHR system, including the Acetabular Cups and Femoral head, were properly implanted in Plaintiffs without any alteration of the BHR system after the system left the control of Smith & Nephew. In the alternative, any changes that were made to the BHR System implanted in Plaintiffs were reasonably foreseeable to Defendant.

603. As a direct and proximate result of Smith & Nephew's BHR manufacturing defects, and as a direct and proximate result of each and every state's laws as set forth above, a BHR system including the Acetabular Cups and Femoral Head, was implanted in Plaintiffs and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiffs as defined in 21 C.F.R. 803.3. As a direct result, Plaintiffs endured pain and suffering and have required additional and debilitating surgeries and have incurred significant medical expenses in the past and will incur additional medical expenses in the future; both past and future wage loss; loss of consortium; physical pain and suffering, both past and future mental anguish and emotional distress, both past and future, including, but not limited to, humiliation, embarrassment, annoyance and aggravation.

COUNT IX
PUNITIVE DAMAGES

604. Plaintiffs herein incorporate, reassert and re-allege the allegations set forth above by reference as if fully set forth herein below.

605. The acts and omissions of the Defendant as set forth herein constitute intentional, fraudulent, malicious and/or reckless conduct. Accordingly, Plaintiffs are entitled to an award of punitive damages.

WHEREFORE, Plaintiffs pray that this Court enter judgment against the Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), together with pre-judgment and post judgment interest, attorneys' fees and costs of this action as may be recoverable, and for such further relief as this Court deems just and reasonable.

Dated: August 11, 2017

Respectfully Submitted,

/s/ Robert K. Jenner

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 11th day of August, 2017, that I electronically filed the foregoing with the Clerk of the Court by using CM/ECF. Notice of this filing will be sent by e-mail to all parties by operations of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic filing. Parties may access this filing through the Court's CM/ECF system.

/s/ Robert K. Jenner
Counsel for Plaintiffs